PURPOSE: To assess the efficacy and safety of implanting a secondary intraocular lens (IOL) in the ciliary sulcus to correct pseudophakic ametropia.

SETTING: Department of Ophthalmology, Medical University of Vienna, Vienna, Austria.

METHODS: This prospective nonrandomized study included patients who had implantation of a secondary IOL (Sulcoflex 653L) to correct residual refractive error after phacoemulsification with IOL implantation in the capsular bag. After implantation of the secondary IOL in the ciliary sulcus, visual and refractive outcomes were evaluated. Inflammation was measured with a laser flare–cell meter. The position and rotation of the IOLs were documented at all control visits, and Scheimpflug images were taken. Postoperative follow-up was at 1 week and 1, 6, 12, and 17 months.

RESULTS: Twelve eyes of 10 patients were evaluated. The mean spherical equivalent decreased from –1.25 diopters (D) ± 0.25 (SD) (range –2.00 to +4.00 D) preoperatively to –0.25 ± 0.40 D (range –0.50 to +0.25 D) postoperatively. Uncorrected distance visual acuity improved in all cases. There were no significant intraoperative or postoperative complications.

CONCLUSIONS: Sulcus implantation of the secondary IOL to correct pseudophakic refractive error was safe and predictable. The IOL was well tolerated in all eyes.

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Despite advances in intraocular lens (IOL) power calculation formulas and the availability of accurate biometry techniques, pseudophakic refractive errors are unavoidable in some cases. In 1993, Gayton and Sanders¹ first described the piggyback IOL technique to provide adequate power in highly hyperopic patients. The technique was extended to secondary cases in which additional power is added or subtracted in an underpowered or overpowered pseudophakic eye. Since then, many surgeons have used piggyback IOL implantation in less extreme cases of hyperopia in which a single IOL could not give the required power.

Implanting 2 piggyback IOLs in the capsular bag raises concerns about the risk for interlenticular opacification (ILO) with Elschnig pearl proliferation in the peripheral interface between 2 IOLs.²⁻⁴ This complication can decrease vision secondary to a postoperative hyperopic shift and cause opacification. Several methods to prevent ILO in eyes with piggyback IOLs have been discussed. One is to place the primary IOL in the capsular bag and the secondary IOL in the ciliary sulcus. The first IOL is implanted in the bag posterior to the continuous curvilinear capsulorhexis edge to help isolate lens equatorial cells from the interlenticular space.⁵,⁶

This study evaluated the visual outcomes and safety of the newly introduced IOL designed for implantation in the ciliary sulcus to correct pseudophakic refractive errors in the pseudophakic eye. The IOL was implanted using a piggyback technique.
PATIENTS AND METHODS

This prospective nonrandomized study included pseudo-phakic patients who had unsatisfactory far distance vision with spectacles. The study was performed at the Department of Ophthalmology, Medical University of Vienna, between May 2007 and October 2008 according to the principles of the Declaration of Helsinki and good clinical practice guidelines. All patients provided written informed consent before surgery, and the local ethics committee approved the study. Only patients without preexisting ocular pathology other than previous cataract extraction by phacoemulsification with in-the-bag IOL implantation were selected. Patients with more than 1.00 diopter (D) of corneal astigmatism were excluded.

Preoperative Assessment

Before surgery, all patients had a complete eye examination that included uncorrected (UDVA) and corrected (CDVA) distance visual acuity, Goldmann applanation tonometry, and fundoscopy. The axial length (AL), anterior chamber depth (ACD), back vertex distance, and keratometric values were determined using biometry (IOL-Master, Carl Zeiss Meditec). The power of the secondary IOL was determined using the Haigis formula based on ACD and effective lens power. 

Intraocular Lens

The secondary IOL in this study was a foldable aspheric model designed for fixation in the ciliary sulcus (Sulcoflex 653L, Rayner Intraocular Lenses Ltd.) (Figure 1). The single-piece hydrophilic acrylic IOL has an overall size of 13.5 mm. The 6.5 mm optic has a rounded edge and a concave posterior surface. The haptics have 10 degrees of posterior angulation and an undulating configuration with rounded edges.

Surgical Technique

The same surgeon (M.A) performed all secondary IOL implantations through a self-sealing clear corneal incision (2.75 mm) under topical and intracameral anesthesia using a standardized technique. Before surgery, pupils were dilated with tropicamide, phenylephrine hydrochloride 2.5%, cyclopentolate 1.0%, and diclofenac sodium 0.1%. The anterior chamber and retroiridial space were filled with sodium hyaluronate 1% (Healon). The secondary IOL was implanted in the ciliary sulcus using the supplied 1-piece single-use injector. The surgeon then checked to ensure the IOL was well centered. The ophthalmic viscosurgical device was washed out, acetylcholine 1% was injected intracameraly, and cefuroxime 1.0 mg (0.3 mL) was administered. After surgery, all patients received topical gentamicin–dexamethasone and diclofenac sodium 0.1% eyedrops 3 times a day for 4 weeks.

Postoperative Assessment

Postoperative examinations were performed at 1 week and 1, 6, 12, and 17 months. The primary outcome measures were UDVA, CDVA, and complications. A laser flare–cell meter (FC-1000, Kowa Co., Ltd.) was used to measure anterior chamber inflammation at each visit. The measurements were taken after visual acuity was tested and 20 minutes after administration of phenylephrine 2.5% and tropicamide 0.5%.

At slitlamp examination was performed using a standardized evaluation form and the following were subjectively assessed: IOL position and centration, distance between the iris and the secondary IOL, distance between the primary IOL and the secondary IOL, haptic position, and pigment dispersion. At each visit, digital retroillumination images of the IOLs were obtained using a digital camera (Nikon/Kodak NC2000e, Eastman Kodak Co.) mounted on a modified Zeiss 30 slitlamp (Carl Zeiss Meditec) with an external light and flashlight source. The flashlight provides coaxial illumination from a flash pack through a fiber-optic cable to the camera. RotatingScheimpflug photographs (Pentacam, Oculus Optikgeräte GmbH), and in some cases ultrasound biomicroscopy (UBM) images, were taken. Intraocular pressure (IOP) measurement was followed by a retinal examination.

RESULTS

The study evaluated 12 eyes of 10 patients. The median age of the 6 women and 4 men was 53.58 years (range 32 to 74 years). Table 1 shows the patients’ demographics and power of the secondary IOL. The mean follow-up after secondary IOL implantation was 12 months (range 6 to 17 months).

The residual refractive error ranged from $-2.00$ D to $+4.00$ D. The mean spherical equivalent decreased from $-1.25 \pm 0.25$ (SD) (range $-2.00$ to $+4.00$ D) preoperatively to $-0.25 \pm 0.40$ D (range $-0.50$ to $+0.25$ D) postoperatively. All patients had improved UDVA postoperatively; the mean Snellen UDVA
1 month postoperatively was 0.9 ± 0.1, which remained stable throughout the study.

Three eyes (25.0%) had a neodymium:YAG (Nd:YAG) laser capsulotomy before secondary IOL implantation. Two eyes (16.6%) of 1 patient had implantation of a refractive multifocal IOL (Acri.Sil 737D, Acri.Tec GmbH) (Figure 2).

All surgeries were uneventful. One eye (8.3%) had an IOP increase to 28 mm Hg on the first postoperative day. After 7 days of dorzolamide hydrochloride timolol maleate eyedrops twice daily, the IOP was 12 mm Hg and the antiglaucoma therapy was discontinued. The IOP remained stable (maximum 16 mm Hg) throughout the follow-up (17 months). No other eye had increased IOP postoperatively.

No signs of pigment dispersion, iris bulging, foreign-body giant cell formation, or ILO were observed during the follow-up (Figure 3). Decentration of the secondary IOL occurred in 1 eye (8.3%); the decentration was less than 0.5 mm 1 day postoperatively and remained stable throughout the follow-up (17 months). The other IOLs were well centered at all postoperative visits. There were no cases of IOL rotation or tilt. The Scheimpflug images showed the same IOL lens distances at all postoperative visits (Figure 4). The UBM images confirmed that the IOL position was stable in all cases (Figure 5).

Table 2 shows laser flare values over time. There was no significant difference between the preoperative value and any postoperative value.

**DISCUSSION**

Before cataract surgery, patients have high visual expectations. Postoperative residual refractive error is frustrating for surgeon and patient. Our results show that secondary IOL implantation in the ciliary sulcus is safe, less traumatic, and predictable in correcting pseudophakic refractive errors. A study by Habot-Wilner et al. found that piggyback implantation of an appropriate IOL in the ciliary sulcus is a reasonable option for correcting pseudophakic refractive error, and our results confirm this.

Werner et al. suggest that implantation of a posterior IOL in the capsular bag and an anterior IOL in the ciliary sulcus prevents ILO formation. The results in our pilot study agree with this because no eye developed ILO. In all eyes, the distance between the primary IOL and secondary IOL remained stable over the postoperative follow-up. We used Scheimpflug photography to evaluate the distance between the optics of 2 IOLs, although the method did not allow assessment of the relationship between the haptic and the iris. The Scheimpflug photography showed a well-centered IOL except in 1 case (eye 1), in which the secondary IOL was decentralized by less than 0.05 mm. The distance was always good in the optic zone (Figures 6 and 7). The eye with slight IOL...
decentration had an AL of 31.53 mm. We believe that the eye’s large ciliary diameter and weak zonular support caused the secondary IOL to decenter, which did not negatively affect the patient’s vision. We also believe that the posterior concave design of the secondary IOL prevented contact between and distortion of the optical zones.

Implanting a secondary IOL with thick haptics and square-edged haptics or optic in the ciliary sulcus may cause sulcus irritation followed by pigment dispersion. The incidence of pigment dispersion syndrome, iris chafing syndrome, and intermittent uveitis–glaucoma–hyphema syndrome is higher after secondary IOL implantation in the ciliary sulcus.9,10 Pigment dispersion has been observed when the optic margin or haptics chafe against the iris pigment epithelium. In our study, no eye had signs of pigment dispersion or iris chafing. This is because the haptic and optic edges of the secondary IOL are rounded. Also, the haptics have a posterior angulation of 10 degrees, keeping the optic away from the iris. Theoretically, the rounded optic and haptic edges prevent the complications that can occur with single-piece IOLs with square, thick edges and no haptic angulation. At the last follow-up, no eye had damage to the iris. Long-term observation is needed to confirm this observation.

The rotational stability of any sulcus-placed IOL is crucial because rotation in the sulcus not only causes optical distortion, but also increases the risk for ciliary body irritation. This, in turn, can lead to pigment dispersion. The undulating configuration of the outer haptic edges of the secondary IOL was designed to preserve IOL stability and reduce the risk for IOL rotation in the sulcus.

In addition to pigment dispersion, there is a risk for elevated IOP after IOL implantation in the sulcus. One eye in our study (eye 1) had a rise in IOP, which we believe was the result of residual OVD postoperatively.

Secondary piggyback implantation can also cause pupil capture of the optic.11,12 In our study, there were no cases of optic capture because the secondary IOL has a large optic (6.5 mm) with 10 degrees of posterior haptic angulation.

A study by Caporossi et al.13 found that the strength and memory of haptics of 1-piece hydrophobic acrylic IOLs are excellent and that these IOLs can be folded without damaging the haptics during implantation. In addition, the compression force of 1-piece IOLs is low and the decay of this force is more stable than that of IOLs with poly(methyl methacrylate) haptics, which require higher compression forces that diminish rapidly.14 Therefore, 1-piece hydrophilic acrylic IOLs can withstand the stress of implantation through a small incision and thus minimize haptic damage. In contrast, 3-piece IOLs lose their memory in the capsular bag, causing the IOL optic to shift.15,16

Table 2. Laser flare values and differences over time.

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<th>Postop 6 Mo</th>
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evaluation of the relationship between the haptic and iris in 5 eyes showed the secondary IOL was in the sulcus with no iris touch. Despite the flexibility of the IOL’s material, and thus its haptics, the optic is far enough away from the iris–pupil edge because of the high memory of the hydrophilic acrylic material. This may also contribute to the IOL’s stability in the sulcus and the decreased risk for tilt and decentration.

In conclusion, our pilot study found that implantation of a secondary IOL in the ciliary sulcus was safe, causing less trauma to surrounding tissues than would occur after IOL exchange. Follow-up examinations to date have found no complications.

REFERENCES


OTHER CITED MATERIAL

A. Wolfgang Haigis, MS, PhD, personal communication, May 2007).