Clinical and Surgical Outcome of a Supplementary Multifocal Intraocular Lens Implanted with a Bag-In-the-Lens Intraocular Lens: 5-Year Follow-Up

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Keywords

Supplementary intraocular lens · implantation · Rayner sulcoflex · Dysphotopsia · Pigment deposits · Presbyopia correction

Abstract

Introduction: To assess the postoperative outcome and patient-reported satisfaction, spectacle independence, and dysphotopsia after implantation with the multifocal Rayner Sulcoflex supplementary intraocular lens (sIOL). **Materials and Methods:** We analyzed the outcome of all patients implanted with a multifocal sIOL between 2009 and 2011. In all cases, the sIOL was the Rayner Sulcoflex IOL (type 653F) and the primary IOL was a bag-in-the-lens (BIL) IOL. The data were obtained through a retrospective analysis of the patient records and by means of a questionnaire, 5 years after sIOL implantation. **Results:** This study included 31 eyes of 20 patients. In 13 eyes, the sIOL needed explantation ($n = 13$, 41.94%). Dysphotopsia is a frequent complaint (12/15 patients: 80.0%) after sIOL implantation. In 13 out of 31 eyes (41.94%), pigment deposits were found on the sIOL with variable clinical complaints. Five eyes required additional surgery because of clinically significant deposits. **Discus-**

sion/Conclusion: Patients with a multifocal sIOL in combination with a BIL implantation have a higher incidence of dysphotopsia compared to previously published studies. Dysphotopsia was the main complaint and reason for explantation. We encountered a high incidence of pigmentated IOL deposits. The sIOLs can be safely removed even years after implantation.

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Introduction

Monofocal intraocular lenses (IOLs) provide an excellent means through which vision can be restored for a chosen target refraction following cataract or clear lens extraction. One significant limitation of the monofocal approach is that they are usually accompanied by spectacle dependence for other focal points, unless monovision is applied. The “pseudophakic presbyopia,” induced by monofocal implants, is due to their inability to replicate the accommodation seen in the natural crystalline lens. Discovering the perfect lens implant, which would correct presbyopia and provide true spectacle independence, remains a major goal of research. Numerous surgical de-

Table 1. Patient questionnaire (also available in Dutch and French) and results

<i>General</i>		
1. Was the lens explanted in a different center?	(Yes/no)	
2. Did you undergo any other surgeries on your eye(s)?	(Yes/no; if yes specify)	
<i>The visual acuity</i>		
3. How would you evaluate your current vision?	(Weak/reasonable/good/very good/excellent)	
4. How much are you limited by your vision in each of the following activities:	(Not at all/barely/considerably/a lot/made impossible)	
Daily activities?	Watching television?	
Recognizing faces on the street?	Driving during daytime?	
Reading price tags at the store?	Driving during night-time?	
Doing fine work, like knitting?		
<i>Dysphotopsia</i>		
5. How much are you limited by dysphotopsia in each of the following activities:	(Not at all/barely/considerably/a lot/made impossible)	
Your daily activities?	Driving a car?	
Reading reflective paper?	Walking outside?	
<i>Satisfaction</i>		
6. How satisfied are you about your:	(Very unsatisfied/unsatisfied/ neutral/satisfied/very satisfied)	
Distance vision?		
Intermediate vision?	(Definitely not/probably not/neutral/probably/definitely)	
Near vision?	(Definitely not/probably not/neutral/probably/definitely)	
7. Would you have the same lens implanted again?		
8. Would you recommend this lens to a family member or a relative?		
<i>Spectacle independence</i>		
9. Do you wear spectacles or contact lenses during much of the day?	(Yes/no)	
10. Do you wear spectacles or contact lenses during one of these activities?	(Yes/no)	
Daily activities?	Watching television?	
Reading price tags?	Driving a car?	
Reading a book/magazine?		
Questionnaire results – respondents, <i>n</i> = 15 (75%)		
Respondents results	<i>n</i>	%
Explanted	7	47
Satisfaction	8	53
Dysphotopsia	12	80
Mild	6	40
Moderate	4	27
Severe	2	14
Spectacle independence (unexplanted)	6	100

vices and approaches are currently being explored with this goal in mind. The use of multifocal IOLs is increasing the last decade among surgeons seeking to offer their patients a solution to presbyopia. There remains however a significant number of patients who are dissatisfied with the postoperative outcomes and appear to be intolerant for multifocal optics. The most frequent problems reported by patients after multifocal IOLs are as follows: (1) blurred vision due to ametropia, dry eye syndrome, posterior capsule opacification, or a large pupil and (2) dysphotopsia due to IOL decentration. Multifocal lens dissatisfaction is an increasingly common indication for lens explantation. However, these surgeries cannot be pro-

posed lightly to the patients since they account for considerable risks. Whether the advantages of increased spectacle independence outweigh the adverse effects posed by multifocal IOLs appears to vary between patients. Patients' motivation to achieve spectacle independence appears to make them tolerant for compromises [1–5].

Supplementary IOLs (sIOLs) came on the market as an attractive solution to solving refractive surprises and avoiding the complications of IOL exchange procedures. With the advent of these IOLs, in which a second IOL is placed in the sulcus to augment the optical characteristics of a monofocal “in-the-bag” IOL, much hope was put to extend the successful spheric and toric versions to a mul-

Table 2. Patient and eye characteristics

<i>Patient characteristics (n = 20)</i>			
Bilateral	Yes (n = 11; 55.00%)	No (n = 9; 45.00%)	
Sex	Female (n = 10; 50.00%)	Male (n = 10; 50.00%)	
Age, yr	55.60±13.96 [24–77]		
<i>Eye characteristics (n = 31)</i>			
Side	RE (n = 15; 48.39%)	LE (n = 16; 51.61%)	
Comorbidities	Retinal problems (n = 2; 6.45%)	Corneal problems (n = 1; 3.23%)	
Simultaneous implantation	Yes (n = 21; 67.74%)	No (n = 10; 53%)	
Interval, m	28.88±25.84 [5–70]		
Anesthesia	Topical (n = 24; 77.42%)	Retrobulbar (n = 1; 3.23%)	General (n = 6; 19.35%)

tifocal version as an alternative to multifocal IOL implantation [6, 7]. The idea was that in case of patient dissatisfaction, the supplementary IOL could be exchanged very easily. The aim of this study was to examine the 5-year follow-up data of a cohort of patients who had a cataract surgery with primary monofocal IOL implantation and subsequent implantation of a Rayner Sulcoflex multifocal sIOL in the same or different surgical procedure.

Patients and Methods

In this retrospective study, we analyzed the outcome for all patients who received a multifocal Rayner Sulcoflex sIOL following the protocol approved by the Ethics Committee of the Antwerp University (EC protocol 9/39/189). The sIOLs were provided free by the company for the study patients.

All implantations occurred between 2009 and 2011. The data were obtained through a retrospective analysis of the patient records 5 years after follow-up and by means of a questionnaire (Table 1). The questionnaire was based on a protocol approved by the Hospital Ethics Committee (EC protocol 16/45/476).

Preoperative Assessment

All patients underwent a preoperative intake consultation including objective and subjective refraction, visual acuity (best-corrected visual acuity and uncorrected visual acuity) both for near and distance vision, slit lamp examination, intraocular pressure, and biometry: axial length, anterior chamber depth, and keratometry.

Intraocular Lenses

The Rayner Sulcoflex IOL is a 1-piece hydrophilic acrylic lens with undulating C loop haptics and a posterior haptic vaulting of 10°. The optic diameter is 6.50 mm, and overall length is 14.0 mm. Its optic has a convex-concave shape. The multifocal optic has an addition of +3.50 D (the equivalent of a +3.0 D addition at the spectacle plane).

The primary IOL was a bag-in-the-lens (BIL) Morcher 89A IOL for all cases. The BIL IOL is a hydrophilic acrylic monofocal IOL with a unique design and implantation technique [8]. It was developed to prevent posterior capsule opacification and subse-

quent YAG laser capsulotomy. It has a 5.0 mm central optic, which is surrounded by 2 flanges defining a groove allowing suspension of the IOL by both the anterior and posterior capsulorhexes. In 2 eyes, the BIL IOL was toric. All lens surgeries were performed by a single surgeon (M.J.T.).

Postoperative Assessment

Postoperative examinations were performed at 1 week and 1 month. The parameters collected were corrected and uncorrected VA for far and near distance, refraction, intraocular pressure, and eventual complications. Subjective assessment of the position of both IOLs and the grade of inflammation and pigment dispersion was made on slit lamp examination. The ray tracing device at our disposal in that time did not allow for evaluation of internal aberration. This was followed by a retinal examination.

Long-term follow-up was performed by a questionnaire (Table 1). We aimed to analyze the following parameters: patient satisfaction, dysphotopsia, spectacle independence, and IOL explanation. This questionnaire was only used for descriptive statistics.

Results

Demographics

In total, 31 eyes of 20 patients were included in the data analysis (Table 2). No cases operated during that time were excluded. The cohort consisted of 50% female and 50% male with a mean age of 55.60 years ± 13.96 (SD) (range 24–77 years).

The implantation of the primary IOL and the sIOL occurred simultaneously in 21 eyes (67.74%). In 4/21 eyes, the primary IOL was exchanged first for a BIL and a sIOL was then implanted consequently in the same surgical procedure. IOL exchange was performed due to the following: (1) multifocal IOL decentration of primary implanted IOL, (2) intolerance of monovision, and (3) refractive surprise after primary surgery. The rationale to combine IOL exchange and sIOL was to solve the case in 1 and the same surgical procedure.

Table 3. Description of 9 patients with IOL explantation

Patient	Bilateral	Dysphotopsia	IOL deposits	Primary IOL	Interval, m RE/LE
1	No	No	Yes	Morcher BIL 89A	74/–
2	Yes	Yes	Yes	Morcher BIL 89A Toric	2/2
3	Yes	Yes	No	Morcher BIL 89A	2/3
4	No	Yes	No	Morcher BIL 89A	–/2
5	No	Yes	No	Morcher BIL 89A	–/9
6	Yes	Yes	No	Morcher BIL 89A	5/5
7	No	Yes	No	Morcher BIL 89A	–/1
8	Yes	Yes	No	Morcher BIL 89A	1/4
9	Yes	Yes	No	Morcher BIL 89A	11/11

IOL, intraocular lens; BIL, bag-in-the-lens.

In the remaining 10 eyes (32.26%), implantation of the sIOLs occurred in 2 different surgical steps with a mean interval between both surgeries of 28.88 ± 25.84 (SD) (range 5–8 months). In 3 eyes, the primary IOL was a toric BIL.

In 24 eyes of 16 patients (81.08%), the surgery was performed under topical and intracameral anesthesia, 3 patients had bilateral surgery (16.22%) under general anesthesia, and 1 eye of 1 patient was performed under retrobulbar anesthesia (2.70%) because of the combination of vitrectomy, cataract, and sIOL implantation. Both the primary and the sIOL implantation were reported as uneventful surgeries in all 31 eyes.

The indications for unilateral surgery were as follows: (1) unilateral cataract, (2) IOL decentration with dysphotopsia in 1 eye of patients implanted with multifocal IOLs in both eyes and satisfied with their contralateral eye, (3) suppressed amblyopic contralateral eye, (4) intolerance of a previously induced monovision, (5) unsatisfied patients after operation of the first eye and who withdrew the surgery of the second eye, and (6) patients who were already operated in 1 eye with a multifocal IOL.

Preoperative Comorbidities

One patient had a macular scar preoperatively, due to central serous retinopathy 10 years previously, and had normal visual acuity and macula in the other eye. This was the only patient presenting a retinal comorbidity.

Postoperative Visual and Refractive Outcomes

The mean preoperative CDVA available of 28 eyes was 0.86 ± 0.27 (SD) (range 0.05–1.25), and the mean postoperative CDVA visual acuity after 1 month available of 31 eyes was 0.86 ± 0.27 (SD) (range 0.05–1.25). The UDVA

was 0.81 ± 0.28 (range 0.05–1.25) after 1-month follow-up for the same group of eyes. After 1 month, the total mean postoperative spherical refraction was 0.08 ± 0.42 D (range –1 to +0.75) and the total mean cylindrical refraction was -0.38 ± 0.73 D (range –2.5 to 0).

IOL Explantation

The total number of sIOL explantations (Table 3) was 13 eyes (41.93%) of 8 patients (40.0%). Early explantation (<1 year postoperatively) occurred in 12 eyes (38.71%) of 9 patients (45.0%) because of unacceptable subjective dysphotopsia. The mean interval before explantation was 3.92 ± 3.18 months (SD) (range 1.00–11.00 months). All patients were subjectively relieved after explantation except 1 whose visual complaints persisted. One patient underwent late explantation because of pigment deposits on the sIOL. In this case, the time interval before explantation was 74 months. The mean follow-up of the eyes without explantation ($n = 18$ eyes; 58.06%) was 35.39 months ± 29.12 (SD) (range 0.00–84.00).

IOL Deposits

There were 13 eyes (41.94%) of 8 patients in our series in which deposits were found on the sIOL with variable clinical complaints of which the detailed description is summarized in Table 4. Three eyes of 2 patients (patient 1 and 3) underwent explantation of the sIOL based on the severity of their subjective complaints and impossibility of surgical cleaning of the sIOLs.

In the first explantation case (Fig. 1, 2), the patient was planned for sIOL surface cleaning. Preoperatively, it became obvious that the deposits on the sIOL were impossible to clean, justifying the subsequent sIOL removal. Even after explantation, it was not possible to remove the

Table 4. Description of 8 patients with IOL deposits

N = 13	Clinical appearance	Therapy	Interval, m	
			diagnosis	surgery
Patient 1 (unilateral)	Extensive protein deposits on anterior sIOL surface and in the IL interface	Cleaning sIOL surface was unsuccessful, so the sIOL was removed	RE: 71	RE: 74
Patient 2 (unilateral)	Moderate pigment deposits on anterior sIOL surface	Bilateral IOL removal because of combined bad image quality	RE + LE: 1	RE + LE: 2
Patient 3 (bilateral)	Pigment membrane on the anterior sIOL surface and in the IL-interface	Bilateral peeling and cleaning of pigment membrane. No removal	RE + LE: 82	RE: 83 LE: 84
Patient 4 (bilateral)	Minor pigment deposits on anterior sIOL surface	Bilateral Nd:YAG + PI	RE + LE: 13	RE + LE: 30
Patient 5 (unilateral)	Minor pigment deposits on anterior sIOL surface	No intervention	RE: 7	na
Patient 6 (bilateral)	Minor pigment deposits on anterior sIOL surface	No intervention	RE + LE: 12	na
Patient 7 (bilateral)	Minor pigment deposits on anterior sIOL surface	No intervention	RE + LE: 18	na
Patient 8 (unilateral)	Minor pigment deposits on anterior sIOL surface	No intervention	RE: 1	na

IL, interlenticular; IOL, intraocular lens; sIOL, supplementary intraocular lens; PI, peripheral iridotomy, Nd:YAG, neodymium-doped yttrium aluminum garnet.

Fig. 1. Protein deposits on explanted Rayner Sulcoflex sIOL (patient 1, sIOL after explantation; white background). sIOL, supplementary intraocular lens.

Fig. 2. Protein deposits on explanted Rayner Sulcoflex sIOL (patient 1, sIOL after explantation; black background). sIOL, supplementary intraocular lens.

deposits of the sIOL using a soft brush. The IOL was sent to the John A. Moran Eye Center for further examination in the hope to discover the possible cause and composition of these deposits. They were organized in a round/linear configuration on the anterior surface of the sIOL and had the appearance of protein deposits. Energy-dispersive X-ray spectroscopy confirmed that they were not calcium phosphate deposits. The patient did not wish to

be re-implanted with a sIOL and preferred to settle with reading glasses.

In the second explantation case (patient 2), sIOLs showed mild deposits (images not available) and were removed from both eyes on patients' request because of subjective bad quality of vision. The anterior lens deposits in both eyes were clinically compatible with pigment dispersion. The diagnosis was supported by pigment in the anterior chamber

Color version available online

Fig. 3. Pigmented membrane on anterior surface of Rayner Sulcoflex sIOL. (patient 2; right eye, clinical image with normal pupil). sIOL, supplementary intraocular lens.

Color version available online

Fig. 4. Pigmented membrane on anterior surface of Rayner Sulcoflex sIOL. (patient 2; right eye, clinical image with mydriatic pupil). sIOL, supplementary intraocular lens.

Color version available online

Fig. 5. Pigmented membrane on anterior surface of Rayner Sulcoflex sIOL. (patient 2; left eye, clinical image with normal pupil). sIOL, supplementary intraocular lens.

Color version available online

Fig. 6. Pigmented membrane on anterior surface of Rayner Sulcoflex sIOL. (patient 2; left eye, clinical image with mydriatic pupil). sIOL, supplementary intraocular lens.

angle on gonioscopy. On UBM examination, an area of contact between the sIOL and the iris was observed.

In patient 3 (Fig. 3–6), both eyes developed pigmented membranes on the anterior surface of the sIOL as well as interlenticularly. The anterior membrane could be peeled off with a capsulotomy forceps, and the interlenticular membrane aspirated. The postoperative visual acuity was restored, and the patients' complaints resolved.

The other 5 patients (patient 4–8) did not have any subjective complaints caused by the deposits and were satisfied with their lenses. One of these 5 patients had a peripheral YAG iridotomy to prevent pigmentary glaucoma. The patients did not develop any signs of glaucoma during the follow-up period.

Glaucoma Complications

One patient, who had a sIOL implanted in both eyes, developed open-angle glaucoma in 1 eye. During gonioscopy examination, the anterior chamber angle appeared more pigmented. There were no pigment deposits found on the sIOL and no Kruckenberg's spindle. The glaucoma required medical treatment and laser trabeculoplasty. A second patient, with bilateral sIOL implantation, developed open-angle glaucoma in both eyes, but it could be managed with topical medication.

Retinal Complications

One eye developed transient cystoid macula edema after a combined vitrectomy (for a macular pucker) and implantation of a BIL IOL with a sIOL. Visual outcome reached 1.0 unaided.

A second patient developed bilateral central serous chorioretinopathy 2 years after the sIOL implantation. After spontaneous regression of the subretinal fluid, the visual acuity recovered to 1.0 in both eyes.

Patient Satisfaction, Spectacle Independence, and Dysphotopsia Complaints (Table 1)

The response rate to the questionnaire sent to all patients of this cohort, independently whether they had sIOL explantation or not, was 15 out of 20 patients (6 explanted; 9 not explanted). Based on the questions asked regarding patient satisfaction, 53.3% ($n = 8$) were satisfied about their sIOL implantation (1 explanted because of IOL deposits; 7 not explanted). Regarding spectacle independency, all patients were spectacle independent for far and intermediate distances. The 6 remaining patients with multifocal sIOL were all satisfied with their near vision.

Dysphotopsia was reported in 80.0% of respondents ($n = 12$). Patients estimated their dysphotopsia as mild ($n = 6$), moderate ($n = 4$), to severe ($n = 2$).

Discussion

The latest results of modern multifocal IOLs improved dramatically because better care is taken to patient selection, patient education, and weighing multifocal IOL benefits and side effects. However, there is still a considerable percentage of patients that are not satisfied or are feeling miserable after multifocal IOL implants. These patients will occasionally seek for surgeons willing to perform an IOL exchange.

An advantage of the supplementary IOLs (also known as secondary or additional IOLs) is their position in the sulcus in contrast to the classic piggyback technique,

which requires implantation of both the primary and secondary IOLs into the capsular bag. The classic piggyback technique was associated with a number of complications, namely, interlenticular opacification (ILO) [9–12], postoperative elevation of intraocular pressure, pupillary optic capture after mydriasis [13, 14], iris chafing, pigment dispersion syndrome [15, 16], and secondary pigmentary glaucoma [15, 16]. The implantation of these IOLs in the ciliary sulcus increases the distance between the 2 IOLs significantly, thereby reducing (but not eradicating) lens-lens contact and the possibility of ILO.

At the time of writing, there were 3 supplementary IOLs, all 3 specifically designed for secondary implantation in the ciliary sulcus to correct corneal astigmatism at the lenticular plane, pseudophakic ametropias, or pseudophakic presbyopia: the Sulcoflex (Rayner Intraocular Lenses Ltd., East Sussex, United Kingdom), which was the first to be made commercially available, the Add-on (HumanOptics, Erlangen, Germany), and A4 AddOn IOL (Medicontur Medical Engineering Ltd., Zsámbék, Hungary/1stQ GmbH, Mannheim, Germany). All of the above multifocal sIOL are withdrawn from the market. Only clinical data for the Rayner and HumanOptics lenses were available in the literature. A study was done to assess the performance and stability of the A4 AddOn IOL in cadaver eyes [17]. We further will refer to this category of supplementary IOLs as sIOLs.

The sIOLs main advantages, as described in the literature, can be summarized as follows:

- Reversibility in comparison to laser procedures [18].
- Easy to both implant and explant compared to in-the-bag IOL exchange. However, no data has confirmed this yet [19].
- Easy to calculate the IOL power and good predictability of the refractive outcome since calculation is based on the patient's subjective refraction [20].

Based on this study, we can conclude that explantation of a sIOL went perfectly well in all cases. Not only the procedure went uneventfully but also the postoperative complications were very low. When looking at multifocal sIOLs, its reversibility is an important advantage over a multifocal lens-in-the-bag implantation. The potential complications incurred by classic IOL exchange are indeed avoided with the sIOL solution, such as damage to the zonulae, the posterior capsule, or the anterior hyaloid. This study reports 2 reasons for sIOL removal: bad quality of vision and pigment deposits.

However, only 53% of the patients with multifocal sIOL implantation were satisfied with their visual quality for near. This is a very low number of satisfaction. In this study,

all the lenses that were implanted were study lenses offered for free to the patient as a reversible multifocal option. Patients were informed that in case of unacceptable quality of vision, the lens could be removed. This situation might have biased the patient's decision, being more critical and more demanding regarding quality of their sight, to requesting early explantation. When looking at the satisfaction results of the diffractive multifocal supplementary IOL of HumanOptics AG, satisfaction rates were comparable to the refractive multifocal sIOL of Rayner [19].

Several publications reported the clinical results of the monofocal Rayner Sulcoflex IOL and HumanOptics Add-on IOL for the correction of residual refractive errors or residual astigmatism after cataract surgery or refractive lens exchange. All papers concluded in positive results and high satisfaction rates regarding safety and predictability [21–25].

The Rayner Sulcoflex lens has also been implanted in patients after corneal surgery to improve refractive outcome, especially in patients not suitable for refractive laser correction [26]. To the best of our best knowledge, only 3 papers were published on the clinical results after multifocal Sulcoflex IOL implantation. Schrecker et al. [27] compared the multifocal refractive Sulcoflex sIOL and the diffractive HumanOptics sIOL. Schrecker et al. [18, 28] also compared the multifocal refractive Sulcoflex sIOL with a single diffractive multifocal in the bag IOL. The authors reported a high incidence of mainly mild dysphotopsia. In our series, dysphotopsia was considered severe enough to justify exchange of the sIOL in about 50%. Two other publications [29, 30] had only a few cases of multifocal Sulcoflex IOL implantation (respectively $n = 4$ and $n = 1$). We can conclude that dysphotopsia is mainly related to the multifocal properties of the sIOL and was found in literature in both refractive and diffractive sIOL cohorts of patients.

Schrecker et al. [27] reported an incidence of mild pigment dispersion syndrome of 2 eyes of 2 patients (5.7%) in their patient cohort implanted with the HumanOptics Add-on IOL. Kahraman and Amon [21] reported no cases after a 17-month-long follow-up of 12 eyes implanted. In our population, there was an incidence of pigmentary dispersion secondary to sIOL implantation of 12/31 eyes (41.94%) of 8 patients, varying from mild to severe. We also had 1 secondary pigmentary glaucoma.

Although the Rayner sIOL has been reported to show calcifications [10], this was not the case in our series. The opacification, shown in Figure 1, was due to protein deposits on the surface of the IOL. It is not clear what the nature of the proteins is and whether they are a precursor of IOL calcification.

Sulcus placement of sIOLs seems to reduce the risk of ILO compared to the classic piggyback IOL implantation, but our hypothesis is that more pigment deposits might occur over time. We therefore recommend regular glaucoma screening of the patients implanted with sIOLs.

Evidence of contact between both lenses was not reported in the follow-up data. This is not expected since both surfaces have a different vaulting. Of those cases where anterior segment images were available (most of the exchanged Sulcoflex lenses), there was no evidence of contact between the lenses within the pupillary area. The BIL IOL has a slightly more anterior position in the eye compared to lens-in-the-bag IOLs. The anterior-posterior thickness is 0.12 mm thicker for the corresponding lens-in-the-bag IOL type made from the same biomaterial and of the same power than the BIL type. These parameters might cause a slightly more anterior positioning of the BIL IOL-sIOL complex and as a result more prone to induce pigment release from the iris/uvea.

Because this is a retrospective study, the long-term spectacle independence could only be determined subjectively through a questionnaire instead of vision testing as normally performed through UCVA at near and far. Since patient-reported spectacle independence is highly influenced by daily activities and specific job requirements, straightforward yes or no answers to our question regarding satisfaction were not often obtained (Table 4). The patients who had no early sIOL explantation were still satisfied of their near vision after 5 years' follow-up.

Aberrometry was not performed routinely preoperatively. This is a drawback of retrospective studies as we have limited data available about the alignment of the IOLs. This limits us in drawing conclusions as to the optical causes of the dysphotopsia.

Statement of Ethics

The protocol of the initial study was approved by the Ethics Committee of the Antwerp University (EC protocol 9/39/189). The questionnaire was based on a protocol approved by the Hospital Ethics Committee (EC protocol 16/45/476). The data were obtained through a retrospective analysis of the patient records and by means of a questionnaire, 5 years after sIOL implantation.

Conflict of Interest Statement

Drs. Verdonck, Werner, and Ni Dhubbghaill have no financial or proprietary interest in any material or method mentioned. Dr. Tassignon has an intellectual property in the bag-in-the-lens implant (US patent 6 027 531; EU patent 009406794.PCT/120268) li-

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Author Contributions

Thomas Verdonck: concept & design, data acquisition, data analysis & interpretation, drafting manuscript, critical revision of manuscript, and statistical analysis. Liliana Werner: data analysis & interpretation, critical revision, and final approval. Sorch Ni Dhubhghaill: data analysis & interpretation, drafting manuscript, supervision, critical revision, and final approval. Marie-José Tassignon: concept & design, data analysis & interpretation, critical revision of manuscript, supervision, and final approval.