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Bag-in-the-lens intraocular lens in paediatric cataract surgery: intraoperative and postoperative outcomes

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ABSTRACT.

Purpose: **To report intra- and postoperative surgical outcome using the bag-in-the-lens (BIL) technique in paediatric cataract surgery.**

Methods: **In a retrospective case series, we studied the outcomes of children aged <12 years operated for cataract with the bag-in-the-lens intraocular lens (IOL), with a minimum of 6 months of follow-up.**

Results: **Since 2013, 50 eyes in 30 patients <12 years (20 bilateral and 10 unilateral) have been operated at our department with the BIL technique, with a median follow-up time of 33.5 months (range 6–77). Median age at surgery was 49.5 months (4–139). In one case, the IOL luxated through the capsulorhexes to the vitreous, but could be secured and repositioned as planned without further difficulties. Anterior vitrectomy was necessary in one case due to prolapse of vitreous to the anterior chamber during surgery. No other intraoperative complications occurred. Visual axis opacification (VAO) developed in four eyes (8%). So far, only one of these has needed a reoperation with clearing of the secondary cataract. A complete absence of VAO was thus seen throughout the study period in 92%. In two eyes, postoperative iris capture occurred. In both cases, surgical repositioning of the iris was needed. No eyes developed secondary glaucoma during the study period.**

Conclusion: **The BIL technique seems to be a safe surgical procedure in paediatric cataract, with significantly less complications and need for additional surgery compared with the conventional lens-in-the-bag technique.**

Key words: bag-in-the-lens – intraocular lens – paediatric cataract – surgery – visual axis opacification

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Introduction

Paediatric cataract is a major cause of childhood blindness globally (Wilson et al. 2003). Also in developed countries, this condition remains a great challenge due to several reasons. Compared with cataract surgery in adults, the reduced size of the ocular anatomy and the increased reactivity to intraocular procedures are both major concerns for the surgeon. In addition, there are many other factors that must be taken into account when planning paediatric cataract surgery: timing of the operation, intraocular lens (IOL) implantation or aphakia with postoperative contact lens correction, and calculation of postoperative refraction. Finally, after the surgery, the most difficult part remains: a lifelong follow-up with respect to amblyopia, visual axis opacification (VAO) and secondary glaucoma (Medsinge & Nischal 2015).

All the above-mentioned challenges are particularly enhanced in congenital or infantile cataract. While implantation of an IOL has been widely accepted in cataract surgery in children older than 2 years, there is substantially less consensus on IOL implantation in younger children, particularly the infants. Five-year data from two randomized clinical trials (Plager et al. 2014; Solebo et al. 2018) concluded that aphakia and contact lens correction should be recommended for the youngest age group, due to a substantial higher incidence of visual axis opacification in the eyes operated with implantation of an IOL (40% and 39%, respectively) compared with those who were left aphakic and treated with contact lenses (4% and 12%, respectively). A recent review article on behalf of the American Academy of Ophthalmology (Lambert et al. 2019) concluded similarly.

It is important to point out that, so far, all randomized trials comparing implantation of IOL versus aphakia in infants have used the conventional lens-in-the-bag technique, which

includes posterior capsulorhexis and anterior vitrectomy.

In 2002, the Belgian research group of Tassignon and co-workers published their first experiences with a new IOL design, the so-called bag-in-the-lens (BIL) IOL (2002). The BIL intraocular lens has an interhaptic groove along the lens circumference, in which both the anterior and posterior capsules are placed, thus closing the capsular space. This requires both an anterior and posterior capsulorhexis with equal diameter. The same group has pointed out that this surgical concept is especially well suited for cataract surgery in children, as proliferation of remaining lens epithelial cells is altogether prohibited by closing the lens capsule completely, reducing the risk for VAO dramatically. In two publications, they have presented short- and long-term data from children with paediatric cataract operated with the BIL technique (Tassignon et al. 2007; van Looveren et al. 2015). In their most recent publication, 5-year data from 46 eyes (age at surgery 2 months to 14 years) are presented, showing VAO in four cases and glaucoma in one patient (van Looveren et al. 2015). More recently, a Swedish group (Nyström et al. 2018; Nyström et al. 2020), a German group (Lytvynchuk et al. 2020) and a French group (Bailleul 2020) have published their results with the BIL technique in paediatric cataract surgery. Nyström et al. (2018) experienced secondary glaucoma in 13.8% and VAO in 4.6% (median follow-up time 2.9 years, range 7 months to 5.8 years). Lytvynchuk et al. (2020) had 2.2% of secondary glaucoma and 5.6% of VAO; however, their study included only the early postoperative period, defined as 12 months after surgery. The French group (mean follow-up time 3.3 years, range 0.25–9.4 years) reported 5.2% of VAO and no secondary glaucoma (Bailleul 2020).

In spite of these favourable results with the BIL technique, there still seems to be a pending attitude in the paediatric cataract community towards this surgical technique. This is illustrated in a recent broad review article on cataract in children from leading paediatric cataract surgeons (Self et al. 2020), briefly mentioning that the BIL technique seems to give excellent results, but is not widely used. At our department, the BIL technique has been the chosen surgical approach for all paediatric cataract patients (<12 years) since 2013. The aim of this study was to report our intra- and postoperative results.

Materials and methods

Patients

The study was carried out as a retrospective observational case series. Our first patient with the BIL technique was operated in March 2013. Since then, we have operated 156 eyes with cataract (and ectopia lentis) using this technique. Among these, 51 eyes (31 patients) were from patients younger than 12 years with cataract and a minimum follow-up time of 6 months. The BIL technique has been the chosen surgical method in all paediatric cataract surgery at our department during the whole study period. One patient with a unilateral cataract due to toxoplasmosis was lost to follow-up, and thus, the remaining 50 eyes (30 patients) constitute the material of the present study. Due to the relatively limited number of dense congenital cataract in our country (54 000 annual births), infants younger than 3 months who need cataract surgery have so far been referred to Oslo University Hospital; thus, no infants in this age group have been operated at our department. Pre-, peri- and postoperative data concerning the cataract were collected from the electronic patient records. Aetiology, age of onset (defined as the age when the cataract was first diagnosed), laterality, morphology, age at surgery and surgical complications were recorded, as well as important clinical data from the last examination: best-corrected visual acuity (when possible), refraction (retinoscopy or autorefractor) recorded as spherical equivalent and anterior segment findings (with mounted or hand-held slit lamp). In all cases, the intraocular pressure (IOP) was measured with iCare® Model TA01 rebound tonometer (Icare Finland Oy, Vantaa, Finland). All participants co-operated sufficiently to obtain good IOP measurements. From previous studies, it is well known that rebound tonometry overestimates the IOP by approximately 2 mmHg (Muttuvelu et al. 2012). Secondary glaucoma was defined as either having been subject to any glaucoma surgery, or an IOP of ≥22 mmHg and in addition at least one of the following findings: glaucomatous change of the optic disc, myopic change more than normal growth, buphthalmos or corneal oedema.

Median follow-up time was 33.5 months (range 6–77).

Surgical technique

All patients were operated under general anaesthesia and by the same certified BIL surgeon (NEB), using a Zeiss Lumera 700 microscope (Carl Zeiss Meditec AG, Oberkochen, Germany) in combination with either Infinity (Alcon, Texas, United States) or EVA (DORC, Zuidland, The Netherlands) cataract machine. All surgical procedures were video-recorded. The intraocular lens power was calculated (SRK/T formula) using either LenStar® (Haag-Streit, Köniz, Switzerland) or IOLMaster 300® (Carl Zeiss Meditec AG, Oberkochen, Germany) preoperatively, or in the youngest children NIDEK US-1800 A-scan (NIDEK CO., Ltd, Tokyo, Japan) and NIDEK KM-500 autokeratometer (NIDEK CO., Ltd, Tokyo, Japan) measurements immediately prior to the operation. In children older than 12 months, the pupil was dilated preoperatively with cyclopentolate hydrochloride 1.0% and phenylephrine 10% eye drops. In infants, we used cyclopentolate hydrochloride 0.5% and phenylephrine 2.5%. Corneal paracentesis (1.2 mm) was made at 2 and 4 o'clock position. The anterior chamber was filled with Viscoat® (Alcon, Texas, United States) ophthalmic viscosurgical device (OVD). The main incision was made at 12 o'clock, initially 2.2 mm in size. Later, the main incision was abandoned and only two paracenteses were used. One of these was enlarged before the BIL implantation. All incisions had a uniplanar architecture and were placed limbocorneal. The anterior capsule of the lens was stained with trypan blue (VisionBlue®, DORC, Zuidland, The Netherlands), and a guidance ring (Caliper Ring Type 5NO, Morcher®, Stuttgart, Germany) was placed on the anterior lens capsule and fixated with Provisc® (Alcon, Texas, United States) OVD. An anterior continuous curvilinear capsulorhexis (ACCC) was performed within the

guidance ring using a capsulorhexis forceps (K5-5090D, Denzel Medical GmbH &Co, Neuhausen ob Eck, Germany) (Fig. 1A). The lens nucleus and cortex were removed with bimanual irrigation and aspiration (Fig. 1B). The anterior chamber was filled with Provisc® OVD, taking care that the capsular bag was not filled. Using a 30G cannula, a small opening centrally in the posterior capsule was made. The space of Berger was filled with Viscoat® to separate the posterior capsule of the lens from the anterior hyaloid membrane (Fig. 1C). Posterior continuous curvilinear capsulorhexis (PCCC) was made with micro-rhexis forceps (FR-2268, EYE Tech, Essex, United Kingdom) using the anterior capsulorhexis as a guide (Fig. 1D). The main incision was enlarged to about 3 mm in size. A bag-in-the-lens IOL (Type 89A®, Morcher®, Stuttgart, Germany) was implanted through an injector cartridge. With gentle pressure on the IOL, the posterior haptic was engaged through the anterior and posterior capsulorhexes, ensuring that finally both the anterior and posterior capsulorhexis edges were safely placed within the interhaptic groove of the lens (Fig. 1E). Acetylcholine (Miochol-E®, Bausch+Lomb, Bridgewater, USA) was injected onto the iris in order to constrict the pupil and prevent 'pupillary capture'. Both incisions were sutured with Vicryl 10-0, and finally, OVD was removed from the anterior chamber (Fig. 1F). Cefuroxime (Aprokam®, Théa Pharmaceuticals Ltd., Newcastle-under-Lyme, UK) was installed in the anterior chamber at the end of the procedure. All patients were treated with tobramycin–dexamethasone (Tobrasone®, Novartis, Basel, Switzerland) droplets four times daily for 4–6 weeks postoperatively. Pilocarpine 2% droplets were used in cases with shallow anterior chamber to prevent 'pupillary capture'. Control examinations were carried out routinely 1 and 4 weeks postoperatively and thereafter at individually adjusted intervals.

Ethics

The study adhered to the tenets of the Declaration of Helsinki and was approved as a quality improvement study by the Institutional Review Board (ref #2015/4256).

Results

From 2013 until April 2020, 50 eyes from 30 patients <12 years (19 boys, 11 girls) with a minimum follow-up time of 6 months were operated with the BIL technique. Twenty cases were bilateral, while ten were unilateral. Median age of cataract onset was 26.0 months (range 0–128); in 23 cases, the age of onset was less than 24 months. In 29 cases (eyes), the

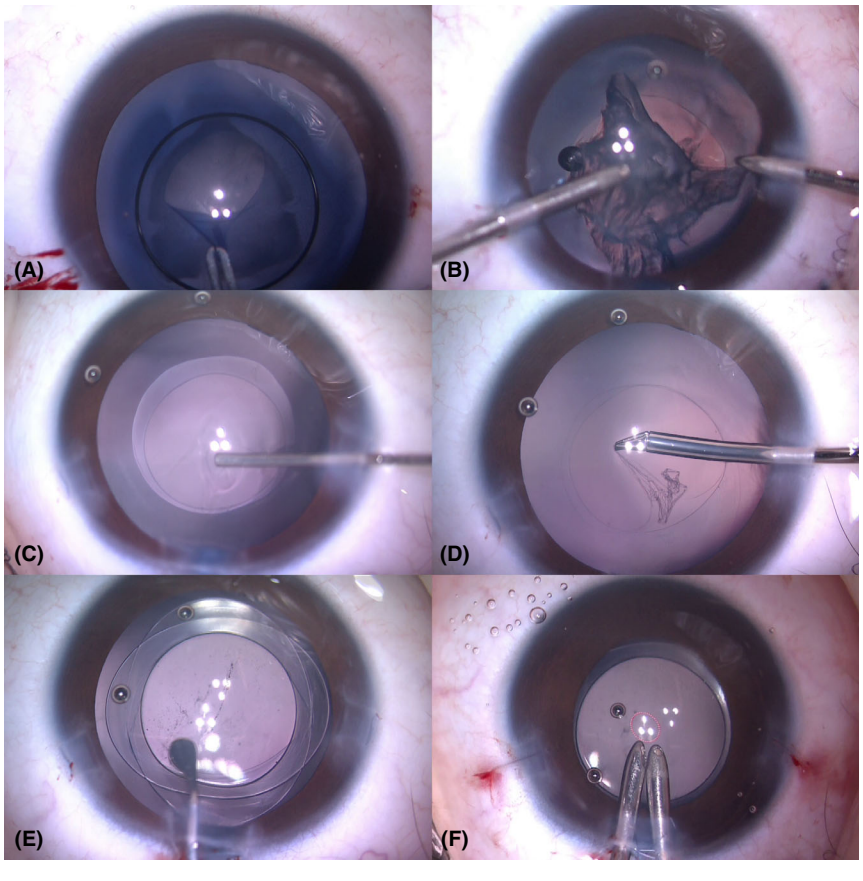

Figure 1. Illustration of the different steps of the bag-in-the-lens surgery in a 2-year-old child. (A) The anterior capsule is stained with trypan blue. A guidance ring is placed on the anterior lens capsule and fixated with OVD (ophthalmic viscosurgical device). An anterior continuous curvilinear capsulorhexis is performed within the guidance ring. (B) The lens nucleus and cortex are removed with bimanual irrigation and aspiration. (C) The space of Berger is filled with OVD after making a small opening centrally in the posterior capsule. (D) A posterior continuous curvilinear capsulorhexis is made using the anterior capsulorhexis as a guide. (E) The bag-in-the-lens IOL is placed with both capsulorhexes within the interhaptic groove of the lens. (F) Finally, OVD is removed from the anterior chamber by bimanual irrigation/aspiration.

cataract was developmental; in 14 congenital cataracts, six were complicated cataracts due to uveitis, and one was traumatic. Among the congenital cases, only one had a bilateral, subtotal dense cataract. This was a boy from Somalia, who was referred at the age of 3 months and operated 3 weeks later. The other congenital cases were anterior pole (4 cases), posterior pole (5 cases) and zonular (4 cases) cataracts that could be operated at a later age. Mean age at surgery in the congenital group was 25.1 ± 17.7 months, median 28.5 (4–58) months. Eight patients had a diagnosed or suspected syndrome; all these cases had bilateral cataract. Median age at surgery in the whole study group was 49.5 months (range 4–139). In six cases, surgery was carried out before 12 months of age. Further details concerning patient characteristics and preoperative biometry data are shown in Table 1.

Intraoperative complications

The surgery was uneventful in all cases but three. In one patient with Stickler's syndrome and excessive myopia, the IOL luxated through the capsulorhexes into the vitreous. It was, however, successfully secured and repositioned during the operation, and the further follow-up has been without complications. In the second case, anterior vitrectomy was needed due to prolapse of vitreous to the anterior chamber during the surgery. The further surgical procedure and later follow-up have been uncomplicated. In the third case, the posterior capsulorhexis was made larger than intended, but IOL implantation went uneventfully. In this case, however, we have later observed VAO (see below), but so far not to such a degree that additional surgery has been needed. It was not necessary to refrain from the planned BIL IOL implantation in any of the surgical procedures in this study.

Table 1. Clinical characteristics of 30 patients with childhood cataract operated with the bag-in-the-lens technique.

Patients (No)	30
Sex, M/F	19/11
Eyes (No)	50 (26 right eyes, 24 left eyes)
Bilateral/unilateral, patients	20/10
Age at onset (months)	
Mean ± SD	39.6 ± 38.5
Median (range)	26.0 (0–128)
Systemic disease, patients	
None	22
Retarded development	3
Stickler syndrome	1
COL4A1 mutation	1
Poland syndrome	1
Saul–Wilson syndrome	1
Unknown syndrome	1
Coexisting ocular disease, eyes	
Uveitis	6
Persisting fetal vasculature	2
Type of cataract, eyes	
Developmental	29
Congenital	14
Complicated	6
Traumatic	1
Cataract morphology, eyes	
Zonular	17
Posterior pole	14
Anterior pole	5
Dense	7
Nuclear	4
Cortical	3
Age at surgery (months)	
Mean ± SD	58.7 ± 40.5
Median (range)	49.5 (4–139)
Keratometry (D), eyes	
Mean ± SD	43.9 ± 2.7
Median (range)	44.0 (35.8–48.5)
Axial length (mm), eyes	
Mean ± SD	21.9 ± 3.0
Median (range)	21.8 (18.4–38.0)
Follow-up after cataract surgery (months)	
Mean ± SD	36.5 ± 21.7
Median (range)	33.5 (6–77)

Postoperative complications

In all cases, slit-lamp examinations on the first postoperative day did not show any case of accentuated inflammatory response in the anterior chamber or need for increased or prolonged steroid medication.

In two cases, iris capture was observed postoperatively, and in both cases, surgical intervention was needed to replace the iris. The first case was a 10-year-old girl with cataract due to anterior uveitis, in which an Ahmed tube had been implanted due to secondary glaucoma 27 months prior to the cataract surgery. Although an apparently uncomplicated cataract surgery, the nasal part of the pupillary margin was captured in the lens groove 2–3 weeks after surgery. In spite of dilating eye drops and the patient in supine position, the iris malposition remained. In the end, the whole iris was caught in the lens groove (Fig. 2). Surgery was performed, successfully positioning the lens behind the iris.

The second case was a zonular cataract operated at 71 months of age

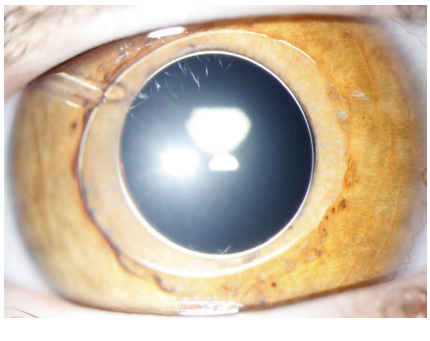

Figure 2. Total iris capture in a 10-year-old child with anterior uveitis in which an Ahmed tube had been implanted due to secondary glaucoma prior to the cataract surgery. The iris capture was solved by lifting the iris out of the interhaptic lens groove and positioning the BIL IOL behind the iris. At the same procedure, a peripheral iridectomy was made.

with uneventful surgery. In this case, iris capture into the lens groove laterally was first discovered 4 months postoperatively. The patient was operated one month later, lifting the iris out of the lens groove. In both cases, a peripheral iridectomy was made to prevent recurrence of the iris capture. Further follow-up has been uneventful. At the last control, all patients had centred IOL.

In another patient with anterior uveitis, trabeculectomy had been performed due to secondary glaucoma 20 months before the cataract operation. In this patient, hyperfiltration of the trabeculectomy with hypotony (2–4 mmHg), hypermetropization and hypotony maculopathy presented 1 week after surgery. After two revisions of the trabeculectomy, the intraocular pressure normalized, and both pressure and visual acuity have been normal since then.

Postoperatively, four eyes (8.0%) have developed some degree of VAO (Figure 3); correspondingly, 42 out of 50 eyes (92%) have preserved a completely clear visual axis after a median postoperative follow-up time of 33.5 months. One of the eyes with VAO was first diagnosed 7 months postoperatively, and due to increasing opacities, the eye had to be reoperated 25 months after the primary surgery. This was done with luxation of the BIL anteriorly to facilitate the removal of VAO manually and with vitrectomy following correct replacement of the BIL in both rhexes. There has been no sign of VAO in this case afterwards. In this case, re-examination of the surgical video showed that the capsulorhexis edges had been incompletely fitted into the lens groove (Fig. 3A). In the second case of VAO, the posterior capsulorhexis was made too wide. This was already recognized intraoperatively (see above). The VAO was first seen 3 months postoperatively as minor dot-shaped opacities in the lower half of the pupil. At subsequent control examinations, the VAO has shown a slight increase (Fig. 3B). At the last control, 39 months after surgery, there was some VAO also centrally in the optic axis, but the best-corrected visual acuity was 0.63 and it was decided to watch and wait. The last two eyes that developed VAO belonged to a 9-year-old boy with significantly short eyes (axial length right eye 18.9 and left eye 19.2 mm). He had Saul–Wilson syndrome, an extremely rare skeletal dysplasia with a known association with cataract. In this patient, a very slight, but evenly distributed, secondary cataract was seen at the whole posterior surface of the IOL 4–6 months postoperatively, similar in both eyes (Fig. 3C,D). So far, the opacities are so subtle that treatment has not been needed.

In one case, the intraocular pressure was elevated to 40 mmHg at the 4 weeks' postoperative examination. Local steroid eye drops were discontinued, and the patient was treated

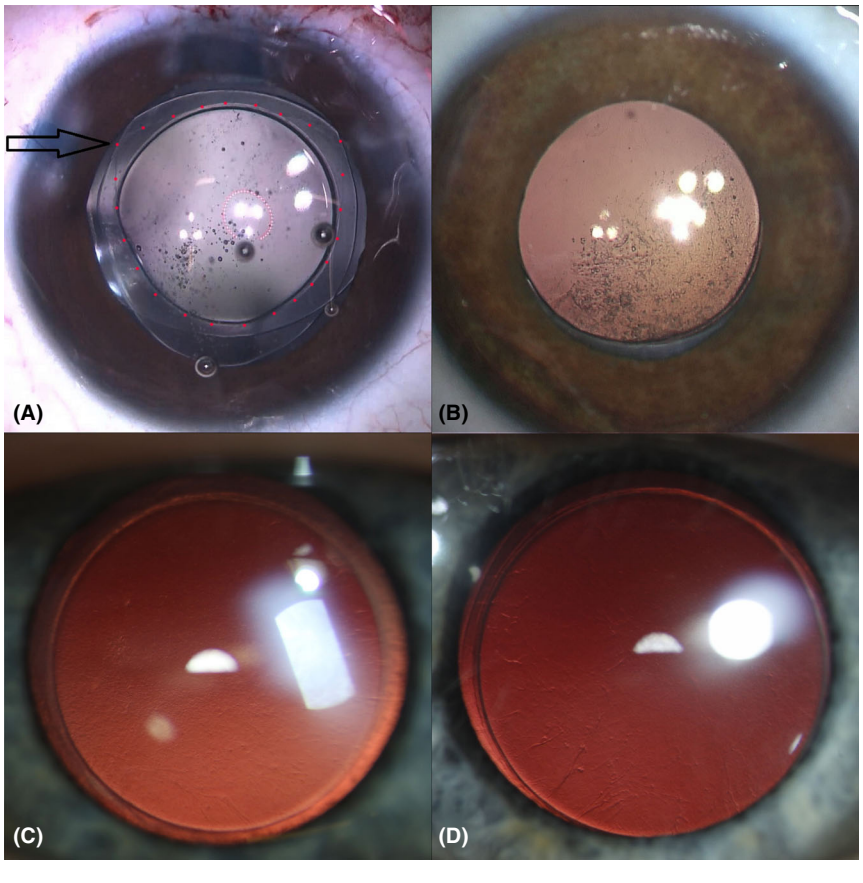

Figure 3. (A) Picture from the surgical video recording in one of the patients developing postoperative visual axis opacification (VAO). The red dotted line shows the posterior capsulorhexis is incorrectly placed behind the BIL superiorly. The arrow shows one of the two places where the posterior capsulorhexis bends out of the lens groove. (B) VAO due to a too large posterior capsulorhexis. (C) and (D) Subtle VAO in both eyes of a child with Saul–Wilson syndrome and short eyes.

Table 2. Postoperative results at the last visit in 30 children (50 eyes) with cataract operated with the bag-in-the-lens technique.

Postoperative status at the last visit	Results
Age in months, median (range)	106 (6–173)
Spherical equivalent (D), eyes (N = 50)	
Mean ± SD	−0.8 ± 1.8
Median (range)	−0.8 (−6.25 to +2.50)
Best-corrected visual acuity, eyes (n = 46)	
mean ± SD	0.63 ± 0.32
median (range)	0.72 (0.05–1.0)
Slit-lamp findings, eyes (N = 50)	
Centred IOL	50 (100%)
VAO	3 (6.0%)*
Intraocular pressure (mmHg) (N = 50)	
Mean ± SD	15.7 ± 3.2
Median (range)	16.0 (6–23)

IOL = intraocular lens, VAO = visual axis opacification.
* Four eyes in the study developed VAO; one of these needed clearing of VAO 25 months after primary surgery, this eye had no further recurrence of VAO at the last examination.

according to standard treatment. Two weeks later, the IOP was normalized, and all anti-glaucomatous medication could be discontinued.

Postoperative status at the last examination

Visual acuity at the last examination (median age 106 months, range 6–173) could be recorded in 46 eyes. In seven eyes, the best-corrected visual acuity was <0.3. In one of these cases, the poor acuity was due to a punch-out macular scar in the left eye of the Stickler patient.

Median postoperative spherical equivalent refraction was −0.94 (range −6.25 to +2.50). The most myopic patient was the Stickler patient, in whom a postoperative refraction of −6 D was predicted, due to the fact that an IOL of +10 D was the weakest lens available at surgery. At the most hypermetropic end of the scale (+2.50) was the patient with Saul–Wilson syndrome with short axial length (19.2 mm at 9 years of age), who received the strongest IOL we had, +30 D, but in whom we also predicted a residual hypermetropia.

Median IOP at the last examination was 16 mmHg (range 6–23). At the last control examination, two eyes (in two different patients) had slightly elevated IOP: one had 22 mmHg, and one had 23 mmHg. There were no additional structural signs of secondary glaucoma in any of these eyes. In the eye with 23 mmHg, the patient has very recently (after closing the study) been to an additional control examination, and the IOP was then 16 mmHg. Further results at the last postoperative examination are presented in Table 2.

Discussion

In this study, 50 eyes in 30 children aged 4 months to 12 years underwent cataract surgery with a bag-in-the-lens (BIL) IOL. In three cases, intraoperative problems occurred, but all these cases got the intended IOL in place and no secondary surgery has been needed. Two patients had to be reoperated due to iris capture, and in one uveitis patient, a trabeculectomy performed prior to the cataract surgery had to be revised due to hyperfiltration and hypotony.

After a median follow-up time of 33.5 months, only four patients (8.0%) have developed some degree of VAO, and only one of these has so far needed reoperation. So far, there are no cases of secondary glaucoma or other complications. These favourable results are in accordance with the other studies on BIL surgery in paediatric cataract (Tassignon et al. 2007; van Looveren et al. 2015; Nyström et al. 2018; Bailleul 2020; Lytvynchuk et al. 2020).

We hypothesize that there are two main reasons why the BIL concept is of particular advantage in paediatric cataract: (1) by joining the anterior and posterior capsulorhexis edges in the lens groove, the lens capsule is virtually sealed, preventing any remaining lens epithelium cells from proliferating towards the optical axis. Thus, the need for reoperations is significantly reduced and the risk of amblyopia development is markedly diminished. In favour of this hypothesis is the fact that in two of three patients in which VAO developed, re-examination of the surgical video revealed that the anterior and/or the posterior capsulorhexes were not properly placed in the IOL lens groove. In the third patient with VAO in both eyes (Figure 2C and D), we think the reason for VAO development is related to short eyes and narrow Berger's space with insufficient separation of the posterior capsule from the anterior hyaloid membrane. It is interesting that both van Looveren et al. (2015) and Lytvynchuk et al. (2020) also concluded that in all their cases of VAO, the posterior capsule was not or no longer completely inserted into the IOL groove. (2) Because anterior vitrectomy is avoided in the BIL surgery, the anterior vitreous membrane is kept intact. In this way, the natural barrier between the anterior and posterior segments of the eye is preserved. In the conventional lens-in-the-bag paediatric cataract surgery, anterior vitrectomy is regarded a necessary and important part of the operation, in order to minimize the frequency of VAO (Cao et al 2019). Although only a hypothesis, we find it likely to assume that an intact vitreous membrane may contribute to the low frequency of postoperative complications, especial secondary glaucoma and postoperative inflammation. Further research is needed to explore this hypothesis.

Our results are in line with previous findings showing that the BIL technique in paediatric cataract surgery dramatically lowers the frequency of VAO to values well below 10%, and thus significantly minimizes the need for additional surgeries. In addition, a majority of the studies on the BIL technique in paediatric cataract surgery indicate a lower frequency of secondary glaucoma. These facts strongly suggest that if a primary implantation of an IOL in paediatric cataract surgery is chosen, the bag-in-the-lens should be the preferred technique.

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