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Analysis and management of intraoperative and early postoperative complications of bag-in-the-lens intraocular lens implantation in different age groups of paediatric cataract patients: report of the Giessen Paediatric Cataract Study Group

Lyubomyr M. Lytvynchuk Maximilian V. Thiele and Birgit Lorenz

Department of Ophthalmology, Justus-Liebig-University Giessen, University Hospital Giessen and Marburg GmbH, Giessen, Germany

ABSTRACT.

Purpose: **To report the rate and management of intra- and early postoperative complications of bag-in-the-lens intraocular lens (IOL) implantation technique for cataract treatment in paediatric patients of different age groups.**

Settings: **Department of Ophthalmology, Justus-Liebig-University Giessen, University Hospital Giessen and Marburg GmbH, Campus Giessen, Giessen, Germany.**

Design: **Retrospective non-randomized consecutive case series.**

Methods: **Ninety eyes of 60 paediatric cataract patients were enrolled to this retrospective non-randomized observational consecutive case series single-centre study. All patients underwent cataract surgery with bag-in-the-lens IOL implantation between January 2008 and December 2018, performed by two experienced surgeons. The entire cohort was divided into four age groups: first – 0–<3 months, second – 3–<12 months, third – 12–<36 and fourth – >36 months–17 years of age. The intra- and postoperative complications were based on the clinical records. The description of management of complications related specifically to bag-in-the-lens IOL technique was based on the 39 consecutive cases operated since 1 Jan 2016 by one single surgeon that were all video documented. The early postoperative period was defined as 12 months after surgery.**

Results: **Overall, there were 27 unilateral and 33 bilateral surgical cases of 24 female and 36 male children. The mean age at surgery was 45.25 months (range 1–200 months). The most common intraoperative events were vitreous prolapse and anterior capsule rupture with 28.9% and 13.3%, respectively. Within 12 months of follow-up, five eyes (5.6%) were re-operated because of visual axis reo-pacification (VAR). Intraocular hypertension was diagnosed in seven eyes (7.8%), including two cases that required surgical treatment. In all cases with intra- and early postoperative complications related specifically to bag-in-the-lens technique, it was possible to manage them and successfully implant bag-in-the-lens IOL.**

Conclusions: **Implementation of bag-in-the-lens technique in the treatment of paediatric cataract was associated with a relatively low rate of intra- and postoperative complications, including rare cases of VAR. The correct management of complications related specifically to bag-in-the-lens IOL implantation technique shall to be considered during the learning curve.**

Key words: bag-in-the-lens intraocular lens – intraoperative and postoperative complications – iris capture – paediatric cataract – vitrectomy

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Introduction

Diseases of the lens in paediatric patients (including different forms of paediatric cataract and lens dislocation) are considered to be one of the main causes of child blindness (Foster & Gilbert 1992; Chan et al. 2012; Haargaard et al. 2015; Solebo et al. 2017). Due to the progress in modern cataract surgery, the majority of paediatric cataract cases can be successfully treated decreasing the rate of visual disability (WHO 1977, Wilson et al. 2003; Zetterström & Kugelberg 2007; Nihalani & VanderVeen 2010). Still the visual and anatomical outcomes after cataract surgery in this age group are strongly correlated with the aetiology of the cataract, concomitant ocular or/and systemic diseases, age at surgery and postoperative visual rehabilitation (Bradford et al. 1994; Eriksen et al. 2006; Kirwan & O'Keefe 2006; Birch et al. 2009). A conventional lens-in-the-bag technique or lensectomy with postoperative aphakia are the most used surgical approaches (Zetterstrom et al. 2005; Haargaard et al. 2009; Kim et al. 2012; Gupta et al. 2014; Kuhli-Hattenbach et al. 2016). Additionally, an optic capture technique with implantation of posterior chamber intraocular lenses (IOL) has been implicated in paediatric cataract surgery (Gimbel 1996). One of the main challenges of postoperative pseudophakia and aphakia management is adequate postoperative visual rehabilitation that defines the further development or restoration of visual functions (Bradford et al. 1994; Eriksen et al. 2006). Intra- and postoperative complications related to cataract surgery, such as posterior capsular opacification, ocular hypertension, uveitis and retinal detachment, play an important role to reach best possible anatomical and functional results (Gradin & Mundia 2011; Vasavada et al. 2011; Freedman et al. 2015; Agarkar et al. 2017). Postoperative posterior capsular opacification and visual axis re-opacification (VAR) in cases of lens-in-the-bag with or without posterior capsulorhexis belong to the most frequent complications (Tassignon et al. 1996; Hosal & Biglan 2002). The management of the posterior capsular opacification and VAR in children remains a difficult task (Vasavada et al. 2011). Even when treated successfully, a risk of recurrence still exists. The bag-in-the-lens technique, first introduced by Tassignon et al. (2002), aims to reduce the development of posterior capsular opacification and VAR through the implantation of an innovative IOL design (Tassignon et al. 2002). The surgery first comprises anterior continuous curvilinear capsulorhexis (ACCC) of a well-defined diameter (4.3–5.0 mm) and phacoaspiration. By injecting the ophthalmic viscoelastic devise through the punctured posterior capsule, the anterior vitreous is separated from the posterior capsule. Then, the posterior continuous curvilinear capsulorhexis (PCCC) is performed. The final step of the technique is the implantation of both capsules into the 360 degrees groove of the bag-in-the-lens IOL optic. This makes the residual capsular space closed and epithelial cell proliferation is limited to the periphery of the IOL (Tassignon et al. 2002; Tassignon 2014).

Tassignon et al. (2007) first published the use of bag-in-the-lens IOL implantation in 34 paediatric eyes of 22 children of different age. The main advantage of this technique in children was the reduction of VAR rate compared to other IOL implantation technique. The same group also reported the long-term follow-up results of bag-in-the-lens IOL implantation in 46 eyes of 31 children (Van Looveren et al. 2015). Nyström et al. (2018) recently published a series of 109 eyes of 84 paediatric patients below age 16 years operated with bag-in-the-lens technique. Both groups reported on the postoperative visual and refractive outcomes, as well as the rate of postoperative complications. They concluded that bag-in-the-lens technique appeared to be effective to treat the cataract and prevent VAR in children.

Intraoperative and postoperative difficulties of paediatric cataract surgery with application of lens-in-the-bag technique or lensectomy have been widely reported (Gimbel 1996; Zetterström & Kugelberg 2007; Wilson & Trivedi 2009; Vasavada et al. 2011). With bag-in-the-lens technique, there is still insufficient information regarding BIL IOL power calculations and surgical problems during and after the surgery (Lytvynchuk et al. 2019). The present study aims at analysing the intra- and early postoperative complications in paediatric patients of different age groups that we encountered in our patient cohort (Giessen Paediatric Cataract Study Group). We also describe the management of the complications related specifically to bag-in-the-lens IOL implantation technique and the learning curve associated with the technique.

Patients and Methods

This report is part of a retrospective non-randomized single-centre study (Giessen Paediatric Cataract Study Group). Analysed were the intra- and postoperative complications of paediatric cataract cases operated with bag-in-the-lens IOL implantation at the Department of Ophthalmology, Justus-Liebig University, University Hospital Giessen and Marburg GmbH (Campus Giessen) from Jan 2008 to Dec 2018. This study fully followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Justus-Liebig University, Giessen, Germany (protocol number AZ 166/17).

Patients

The study cohort included 60 consecutive paediatric cataract cases (90 eyes) and was divided into four age groups: first – 0–<3 months, second – 3–<12 months, third – 12–<36 months and fourth – >36 months–17 years of age. The inclusion criteria were: presence of paediatric cataract of different origin and the use of bag-in-the-lens IOL technique with implantation of hydrophilic acrylic IOL Morcher Type 89A (total diameter (TD)/optic diameter (OD) = 7.5 mm/5 mm), Type 89F (TD/OD = 7.5;8.5 mm/5 mm) or Type 89A Toric (TD/OD = 7.5 mm/5 mm) (Morcher GmbH, Stuttgart, Germany). All patients received a standard comprehensive pre- and postoperative examination by an experienced paediatric ophthalmologist, eye surgeon, orthoptist and optician.

Surgery

All surgeries were performed in general anaesthesia by two experienced surgeons (between 2008 and 2015 by WS, 51 eyes (56.7%), and between 2016 and 2018 by LL, 39 eyes (43.3%)). Since 2016, all surgeries were video documented. A standard bag-in-the-lens

IOL implantation technique as proposed by Tassignon et al. (2002) was used in all cases (http://www.morcher.com/nc/en/products/foldable-iols.html Assessed on 28.06.2019). A detailed description of the procedure is given below as certain surgical complications are specifically related to the flow of the surgery.

Eyes with insufficient mydriasis received an intracameral injection of adrenalin (1:1000) and xylocain 2% (0.1 ml) under anaesthesiologic control. In all cases, a temporal incision and additional one or two paracenteses were applied. The main incision was a three step sclerocorneal or limbocorneal incision. The width of the incision was primarily 2.2 mm with widening up to 2.4 mm just before bag-in-the-lens IOL implantation. In cases with small pupil or posterior synechia, flexible iris retractors were used (Alcon Lab., Fort Worth, Texas, USA). After the anterior chamber was filled with sodium hyaluronate 1.2% (NuVisc™ OVD, Beaver-Visitec International, Inc. Waltham, MA, USA), the ring caliper Type 4L (PED) with inner diameter 4.0 mm and outer diameter 4.3 mm (Morcher GmbH, Stuttgart, Germany) was positioned onto the surface of the anterior capsule and centred with regard to the first and third Purkinje reflexes. Then the anterior continuous curvilinear capsulorhexis (ACCC) with diameter $\approx$ 4.3–5.0 mm was performed and the caliper ring then removed. The soft lens was aspirated using bimanual irrigation/aspiration system (Millenium™ Microsurgical System, Bausch&Lomb Inc., Rochester, NY; USA or EVA, DORC, Zuidland, Netherlands). Then, the anterior and posterior capsules were approached to each other with sodium hyaluronate 1.2%. The puncture of the posterior capsule was performed with a 30-gauge needle. The anterior vitreous surface was separated from the posterior capsule with slow directional injection of sodium hyaluronate through the puncture in the posterior capsule followed by posterior continuous curvilinear capsulorhexis (PCCC) with similar diameter to ACCC. The bag-in-the-lens IOL was injected through a 2.2-mm cartridge injection system (Medicel AG, Thal, Switzerland) and both capsulorhexes were inserted into the 360° groove of the bag-in-the-lens IOL using gentle right-to-left and forward and backward movements. In cases with vitreous prolapse an anterior transcorneal 23 or 25 gauge (G) vitrectomy was performed. In all patients under 12 months of age a peripheral superior iridectomy (between 11 and 1 o'clock) was performed using a 23/25 G vitrector. At the end of the surgery the pupil was constricted with injection of Miochol 2–5-mg solution. The corneal wounds were closed with Vicryl 10.0, and 0.025 mg of cefuroxime was injected in anterior chamber (Video 1).

In the postoperative period, all patients received standard medications consisting of eye drops of antibiotics, dexamethasone and non-steroidal anti-inflammatory agents. In every case an early visual rehabilitation was attempted within the first weeks after surgery with prescription of glasses or contact lenses and occlusion therapy as needed.

Analysis of intra- and early postoperative complications

The retrospective study of the intra- and early postoperative complications after bag-in-the-lens IOL implantation procedures was based on review of the clinical documentation and follow-ups of all cases enrolled in the study.

Analysis of the management of intra- and early postoperative complications related specifically to bag-in-the-lens IOL implantation technique was based on the video documentation of the 39 consecutive cases since 2016. An important aim of this analysis was to review the management of bag-in-the-lens IOL-specific complications in order to raise the awareness of the readers who are interested in applying this technique in their practice. The video documentation was performed using a video camera integrated into a Lumera 700 microscope (Carl Zeiss Meditech, Oberkochen, Germany). Analysis of early postoperative complications was based on the photo documentation of the patients' eyes using a RetCam2 (Clarity Medical Systems, Pleasanton, CA) and Slit Lamp BX 900 (Haag-Streit, Bern, Switzerland) performed in all 90 eyes as needed.

Early postoperative period was defined as $\leq$12 months after the surgery. Iris capture was noted when there was incarceration of the iris into the bag-in-the-lens IOL groove. The iris capture was subdivided into two types – partial and total. Visual axis reopacification (VAR) was defined as any opacification occurring on the anterior or posterior surface of the bag-in-the-lens IOL optic or behind the IOL. Postoperative intraocular pressure was measured with two different methods depending on the compliance of the patients and whether the patient was awake or under general anaesthesia. Due to this, the postoperative intraocular hypertension was defined as IOP $\geq$ 12 mmHg measured with applanation tonometry Perkins Tonometer Mk2 (Haag-Streit, Essex, UK) in general anaesthesia or as IOP $\geq$ 20 mmHg with iCare® PRO (Model: TA03, Icare Finland Oy, Vantaa, Finland) in awake state. Secondary postoperative glaucoma on eyes operated with bag-in-the-lens technique was defined according to Nyström et al. (2018) as increase of IOP $\geq$ 22 mmHg measured at the beginning of the induction of general anaesthesia (Tono-Pen XL, Reichard Inc., Depew, NY, USA), and presence of one or more following complications: buphthalmus, enlarged cornea, corneal oedema, glaucomatous appearance of the optic disc, a myopic shift or an increase of axial length more than predicted based on individual growth curves (Zetterberg et al. 2015). Intra- or postoperative bag-in-the-lens IOL dislocation was defined as partial or complete displacement of the ACCC or/and PCCC out of the bag-in-the-lens IOL groove.

Statistical methods

For statistical analysis, a Fisher's exact test was used to examine the associations between two kinds of classifications. The Fisher's exact test of independence allows for analysis of proportions between two nominal variables, depending on the comparison of the other variable, i.e., the hypergeometric distribution is used to calculate the probability of observing a particular arrangement of the data. The null hypothesis (H0) is that the relative proportions of one variable are independent of the second variable and it is mostly employed when sample sizes are small. A disadvantage is that the rejection rate is below the significance level, which can lead to a bigger

chance of an type 2 error. The p-value of <0.05 was considered as statistically significant, for data analysis and presentation, we used R i386 3.3.2, R Core Team (2014) (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patients

The patient demographics are listed in Table 1. Ninety eyes of 60 patients were included to the study. There were 45 right (50%) and 45 left eyes (50%), 24 females (40%) and 36 males (60%). The mean age at the time of surgery was calculated for each age group (Table 1). Unilateral cataract was diagnosed in 27 patients (45%), and bilateral cataract – in 33 patients (55%). In three cases of bilateral cataract, only one eye was operated with the bag-in-the-lens technique. In total, there were 30 children with unilateral surgery and 30 patients with bilateral surgery. Within the entire group, 56 patients (93.3%) were followed up more than 12 months. Four patients (6.7%) were operated at the end of enrolment period and were followed during 8 and 10 months.

Bag-in-the-lens IOL Type 89A was implanted in 83 eyes (92.2%), Type 89F in 5 eyes (5.6%) and Type 89A Toric in 2 eyes (2.2%) (Morcher GmbH, Stuttgart, Germany). For the entire group, the mean power of implanted BIL IOL was 24.78 D (range 8–36.5 D).

Analysis of intra- and early postoperative complications

Type and rate of the intra- and early postoperative complications in the entire cohort and in each age group are displayed in Tables 2 and 3.

In five cases (5.6%) in age group 1 (0–<3 months), due to small palpebral fissure, a lateral canthotomy was performed in order to enlarge the operating field. For this purpose, the Wescott scissors with a single cut of 3–5 mm length were used. Canthotomy enlarged the operating field and created the necessary space for the surgical manoeuvres. There was no bleeding was observed from the canthotomy edges. In all cases, the canthotomy was sutured with two to three absorbable single sutures Vicryl 9.0 (Ethicon, Somerville, NJ, USA) at the end of the surgery with no cosmetic defect postoperatively.

Intraoperative complications

Vitrectomy was performed in 26 cases (28.9%) with vitreous prolapse into the anterior chamber during the surgery (Table 2), including 18 cases (69.2%) in children >12 months. In these cases, a transcorneal vitrectomy was applied. Intracameral injection of triamcinolon acetonid was performed in order to identify residual vitreous strands in anterior chamber. The iris-related complications included two cases of iris haemorrhage (2.2%), two cases of iris prolapse (2.2%) and one case of iris capture (1.1%) (Table 2). In 12 cases (13.3%), a rupture of the anterior capsule occurred, but with limited extent so that the bag-in-the-lens IOL could still be implanted (Fig. 1). The bag-in-the-lens IOL was implanted in spite of posterior capsule rupture as well. Dislocation of the IOL in the anterior chamber after its implantation was noticed in two cases (5%), it was caused by shallowing of the anterior chamber and the IOL then was immediately re-implanted. Persisting mydriasis at the end of the surgery with the size of the pupil larger than the size of the IOL haptic was noticed in seven cases (7.8%). Persisting mydriasis was considered to be a risk factor for postoperative iris capture, in these cases, injection of myochol solution had not resulted in sufficient constriction of the pupil. After sealing of the corneal wounds, pilocarpine 1% eye drops were applied and postoperative check-up was indicated.

For intraoperative complications, a comparison between age groups showed no significant difference with Fischer's test.

Table 1. Epidemiologic characteristics of the study group

Groups	Eyes (*n*)	Patients (*n*)	RE (*n*)	LE (*n*)	Female (*n*)	Male (*n*)	Unilateral surgery (*n*)	Bilateral surgery (*n*)	Mean age, month	Median age, month	Age range, month (min–max)
Entire group	90	60	45	45	24	36	30	30	45.25	21.04	1.05–200.28
0–<3 months	10	6	6	4	4	2	2	4	1.94	1.92	1.05–2.96
3–<12 months	21	14	12	9	6	8	7	7	7.05	6.12	3.19–10.89
12–<36 months	19	14	9	10	6	8	9	5	18.39	17.39	12.07–35.44
>36 months–17 years	40	26	18	22	8	18	12	14	88.88	76.93	36.72–200.28

Table 2. The rate of intraoperative complications during bag-in-the-lens IOL technique in different age groups

Intraoperative complications	Entire group	0–<3 months	3–<12 months	12–<36 months	36 months–17 years
Number of eyes	90	10	21	19	40
Vitreous prolapse	26 (28.9%)*	2 (20%)	6 (28.6%)	9 (47.4%)	9 (22.5%)
Iris haemorrhage	2 (2.2%)	0 (0%)	1 (4.8%)	0 (0%)	1 (2.5%)
Iris prolapse	2 (2.2%)	0 (0%)	2 (9.5%)	0 (0%)	0 (0%)
Iris capture	1 (1.1%)	0 (0%)	0 (0%)	1 (5.3%)	0 (0%)
Anterior capsule rupture	12 (13.3%)	0 (0%)	6 (28.6%)	3 (15.8%)	3 (7.5%)
Posterior capsule rupture	2 (2.2%)	0 (0%)	0 (0%)	2 (10.5%)	0 (0%)
BIL IOL dislocation after implantation	2 (2.2%)	0 (0%)	0 (0%)	0 (0%)	2 (5%)

*Among 26 vitrectomy cases 23 were operated between Jan 2008 and Dec 2015, and 3 cases between Jan 2016 and Dec 2018.

Table 3. The rate of early postoperative complications during bag-in-the-lens IOL technique in different age groups

		Age at the time of the surgery			
Early Postoperative complications≤12 months	Entire group $n = 90$	0–<3 months $n = 10$	3–<12 months $n = 21$	12–<36 months $n = 19$	36 months–17 years $n = 40$
Visual axis re-opacification (VAR)	5 (5.6%)	2 (20%)	1 (4.8%)	1 (5.3%)	1 (2.5%)
Intraocular hypertension[†]	7 (7.8%)	2 (20%)	1 (4.8%)	2 (10.5%)	2 (5%)
Secondary glaucoma	2 (2.2%)	1 (10%)	1 (4.8%)	0 (0%)	0 (0%)
Intrapupillary membrane	1 (1.1%)	1 (10%)	0 (0%)	0 (0%)	0 (0%)
Anterior peripheral synechia	2 (2.2%)	1 (10%)	1 (4.8%)	0 (0%)	0 (0%)
Iris capture	2 (2.2%)	0 (0%)	1 (4.7%)	1 (5.3%)	0 (0%)
Hyphema	2 (2.2%)	0 (0%)	0 (0%)	2 (10.5%)	0 (0%)
Uveitis	6 (6.7%)	0 (0%)	3 (14.3%)	2 (10.5%)	1 (2.5%)
BIL IOL glistening	2 (2.2%)	0 (0%)	0 (0%)	0 (0%)	2 (5%)
BIL IOL luxation	3 (3.3%)	1 (10%)	2 (9.5%)[§]	0 (0%)	0 (0%)
Peripheral corneal opacification	2 (2.2%)	2 (20%)[‡]	0 (0%)	0 (0%)	0 (0%)[‡]

[†]Postoperative intraocular hypertension was defined as IOP ≥ 12 mmHg measured with applanation tonometry Perkins Tonometer Mk2 (Haag-Streit, Essex, UK) in general anaesthesia or as IOP ≥ 20 mmHg with iCare® PRO (Model: TA03, Icare Finland Oy, Vantaa, Finland) in awake state.
[‡]Statistical analysis showed a significant difference with p = 0.037.
[§]In one of two cases in this age group the BIL IOL was dislocated in vitreous cavity.

Early postoperative complications (≤12 months after the surgery)

Visual axis re-opacification (VAR) was noticed in five cases (5.6%) (Fig. 2), with a success rate without VAR of 94.4% (85 eyes) in the entire group. During removal of the VAR, it was noted that the posterior capsule was not or no longer completely inserted into the IOL groove (Video S2). In all five cases, it was possible to remove the re-opacification and reinsert the posterior capsule into the IOL.

Intraocular hypertension defined as described above was documented in seven cases (7.8%) and could be controlled in most cases with topical medications. The distribution of intraocular hypertension in the different age groups is shown in Table 3. A higher incidence of intraocular hypertension was noticed in the youngest age group with a rate of 20%. Secondary glaucoma was documented in two cases (2.2%), and managed with trabeculotomy within 12 months after the bag-in-the-lens IOL implantation.

Iris capture was observed in two cases (2.2%) (Fig. 3). In one case, the iris capture was total and recurrent, and necessitated urgent repeated surgical intervention with reposition of the iris. After the second intervention, the patient received pilocarpin 1% eye drops 1/day for 1 month with reduction of the dose to one drop every 3 days, and thereafter complete tapering. The second case of iris capture was partial (180° of the IOL circumference). It was treated with one single surgical intervention, as the application of mydriatics did not solve the problem. Peripheral anterior synechiae were noticed in two cases (2.2%) and were caused by adhesions between iris and corneal paracentesis (Fig. 4).

Postoperative uveitis was documented in six cases (6.7%). In one patient, on both eyes, there were clinical signs of anterior and intermediate uveitis; however, all tests for infection or other forms of uveitis were negative. The left eye of this patient developed a fibrin reaction in the anterior chamber with formation of fibrin membranes and intraocular hypertension (Fig. 5) and the dense membranes were removed surgically. In the right eye, corneal endothelial precipitates developed with retrolental vitreous opacification and secondary glaucoma. The right eye underwent two glaucoma surgeries (trabeculotomy and implantation of Ahmed valve) till the IOP was sufficiently controlled.

Comparing the data of postoperative corneal opacification between Group 1 (<3 Months) and Group 4 (>36 Months) Fisher's test showed a significant p-value of p = 0.037. We rejected the null hypothesis and noticed that the probability of that complication was dependent on the group, being significantly more likely to appear in younger patients.

The comparisons of all other intra- and early postoperative complication

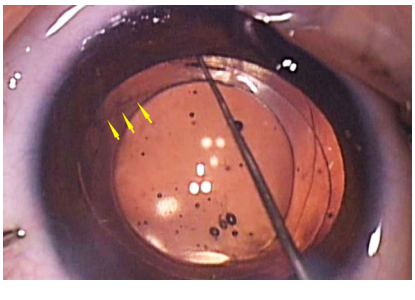

Fig. 1. Implantation of bag-in-the-lens IOL in case of anterior capsulorhexis rupture. Red arrows indicate the tear in the anterior capsulorhexis. Age at surgery 2 years.

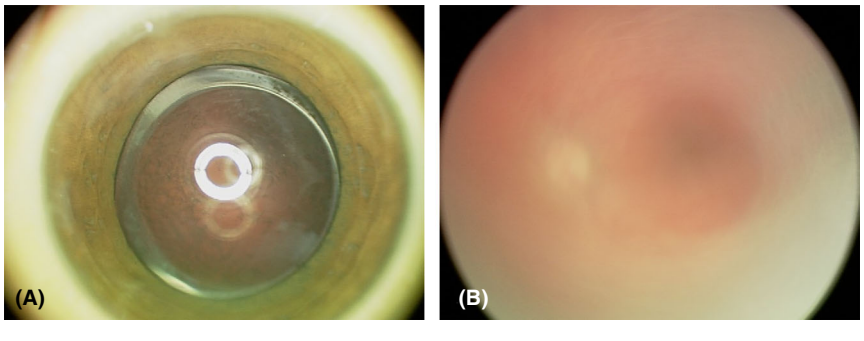

Fig. 2. VAR occurred within first year after bag-in-the-lens IOL implantation. Age at surgery 2 months.

rates between the age groups showed no significant difference with Fischer's test. Still, the probability of wrongly accepting the null hypothesis is quite high.

Management of complications related specifically to the learning curve of the bag-in-the-lens technique

Postoperative analysis of the surgeries of the 39 consecutive cases operated between 2016 and 2018 and based on video documentation of all 39 consecutive cases demonstrated the range of intra- and early postoperative complications related specifically to bag-in-the-lens IOL implantation technique (Table 4). Analysis of the complication rates in dependence to age at surgery was not performed in this subgroup as the number of the cases in each age group was too small.

Management of intraoperative complications

Incision related problems

The size of the main corneal or corneoscleral incision of 2.2 mm was sufficient in all cases for the caliper ring implantation/explantation, ACCC/PCCC performance and phacoaspiration. In the first five cases (12.8%) of the 39 video-documented cases, implantation of the IOL through the 2.2-mm incision was attempted but without success. The implantation of bag-in-the-lens was interrupted due to the insufficient size of the incision, and after enlargement of the incision to 2.4-mm implantation of the IOL was then easy. Enlargement of the incision to 2.4 mm prior to implantation of the IOL has now become a standard. With this technique, implantation of a foldable Type 89A or 89F IOL with optic size 5.0 mm and dioptres ranging from 8 D to 36.5 D was possible in all subsequent cases (Lytvynchuk et al. 2019).

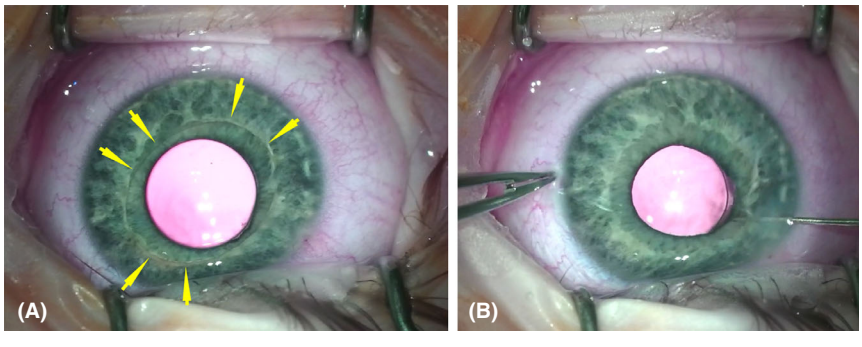

Fig. 3. Circular iris capture in the early postoperative period after implantation bag-in-the-lens IOL Type 89A (A). Surgical reposition of the iris in the same patient (B). Age at surgery 2.7 years.

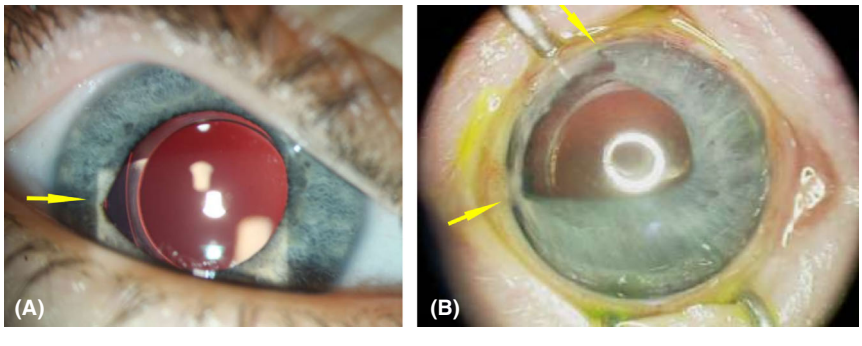

Fig. 4. Deformation of the iris after bag-in-the-lens IOL implantation. A – anterior synechia connected to the main temporal corneal incision (yellow arrow). B – anterior synechia connected to the sites of paracentesis (yellow arrows). Age at surgery 3 years (A) and 3.8 months (B).

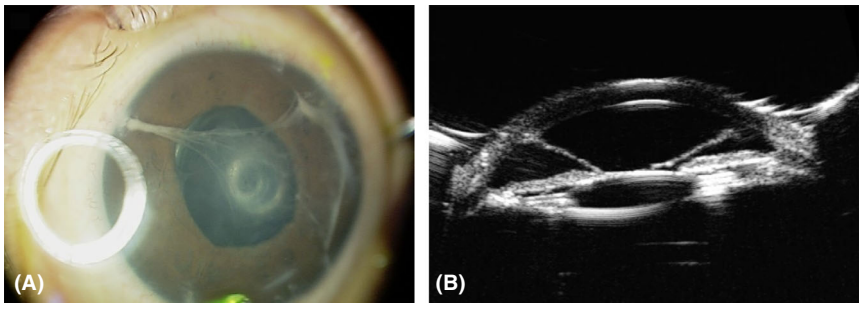

Fig. 5. Anterior uveitis after bag-in-the-lens IOL implantation with fibrin membranes in anterior chamber (AC): Age at surgery 2.7 months. A – colour photo of AC, B – ultrasound biomicroscopy scan.

Caliper ring-related problems

While performing ACCC a slight displacement of the caliper ring was frequent, with the risk of decentration of the capsulorhexis. Adjustment of the caliper ring centration was performed with regard to the first and third Purkinje reflexes. Removal of the caliper ring was associated with its damage in 6 of 39 cases (15.4%), resulting in contact of the sharp edge of the broken ring with the corneal endothelium (Fig. 6 A). In order to avoid this complication, the caliper ring was removed by gripping of the ring with gentle pressure from the jaws of the forceps. The caliper ring was additionally preserved till the end of the surgery. In cases with unintentionally enlarged ACCC and PCCC, the caliper ring was used to recheck the size of the capsule opening in order to choose between 89A and 89F bag-in-the-lens IOL model.

ACCC and PCCC-related problems

In cases with ACCC size 1 mm larger than the caliper ring (>5.3 mm in diameter), we estimated the risk of postoperative bag-in-the-lens IOL dislocation. In 5 of 39 eyes (5.6%) a bag-in-the-lens IOL Type 89F with total diameter of 7.5/8.5 mm and optic diameter of 5 mm was implanted in order to minimize the risk of IOL dislocation.

In 12 of 39 cases (30.8%), ACCC or PCCC were smaller than the caliper ring (<4.3 mm). In 8 of 39 cases (20.5%), an enlargement of the

Table 4. The rate of intra- and early postoperative complications related specifically to the learning curve of bag-in-the-lens IOL technique

	Intraoperative complications related to BIL							Postoperative complications related to BIL			
Number of cases with video documentation	Incision-related problems	Caliper ring-related problems	ACCC oversized	ACCC or PCCC too small	Vitreous viscodissection problems	BIL IOL implantation-related problems	BIL IOL dislocation	BIL IOL damage	Iris capture with posterior synechia	Visual axis re-opacification not	BIL IOL dislocation	BIL IOL precipitates
39 (100%)	5 (12.8%)	6 (15.4%)	5 (12.8%)	12 (30.8%)	4 (10.3%)	5 (12.8%)	5 (12.8%)	1	(2.6%)	2 (5.1%)	2 (5.1%)	1 (2.6%)
2 (5.1%)												

capsulorhexis using anterior chamber scissors and capsular forceps was performed. In 3 of 39 cases (7.7%), without enlargement of ACCC the implantation of bag-in-the-lens IOL led to capsular rupture. However, the IOL remained stable and the capsular rupture did not spread further out.

Vitreous viscodissection problems

In 4 of 39 cases (10.3%), an insufficient viscodissection of the vitreous from the posterior capsule was noticed during IOL implantation. The posterior capsular edge could not be implanted into the groove of the IOL for a segment of the PCCC as the capsule was still attached to the vitreous. In order to proceed with the implantation, a limited anterior vitrectomy in the respective area was performed.

Overfill of retrolental space with sodium hyaluronate 1.2% could cause stretching and rupture of the PCCC. However, if the rupture happens, it is usually limited and partial aspiration of the sodium hyaluronate can be performed. Additionally, an unintended fill of the capsular bag with sodium hyaluronate can result in an increased distance between ACCC and PCCC edges. In such a case, a gentle aspiration of sodium hyaluronate is recommended which allows bringing both capsules again in apposition.

Mydriasis-related problems

In 5 of 39 cases (12.8%), it was impossible to achieve a sufficient mydriasis for bag-in-the-lens IOL implantation technique because of small pupil. In these cases, the separation of posterior synechia was performed with a blunt cannula and the pupil was dilated using 5–6 flexible iris retractors (Alcon Grieshaber, Schaffhausen, Switzerland) (Fig. 6B). The use of iris retractors resulted in local trauma of the pupillary pigment with release of pigment cells in the anterior chamber. However, there were no significant irregularities of the pupil after the removal of the iris retractors. To achieve sufficient mydriasis during the whole surgery in uncomplicated cases, an intracameral injection of mydriatics was used under anaesthesiologic control.

Bag-in-the-lens IOL dislocation

Intraoperative dislocation of bag-in-the-lens IOL was noticed in 5 of 39 cases (12.8%). It was mainly partial dislocation of the IOL haptic in the anterior chamber due to hallow AC at the end of the surgery. This complication was managed by filling of the anterior chamber with sodium hyaluronate 1.2% and re-implantation of the capsulorhexis edges into the bag-in-the-lens IOL groove. Once the IOL was re-implanted, a standard proof of the correct position was performed by gently moving the IOL in four directions in the horizontal plane in order to visualize an incomplete implantation of IOL (Video S3).

Bag-in-the-lens IOL damage

In 1 of 39 cases (2.6%), we observed a crack of the IOL optic. Due to insufficient size of limbocorneal incision, the implantation of bag-in-the-lens IOL was interrupted. After the incision was enlarged, the same bag-in-the-lens IOL (Type 89A) was reloaded into the new injector and the second implantation was performed (Video S4). During this attempt, the bag-in-the-lens IOL fell apart which necessitated the explantation of the broken IOL part through an increased 3-mm incision and implantation of the new bag-in-the-lens IOL (Type 89A).

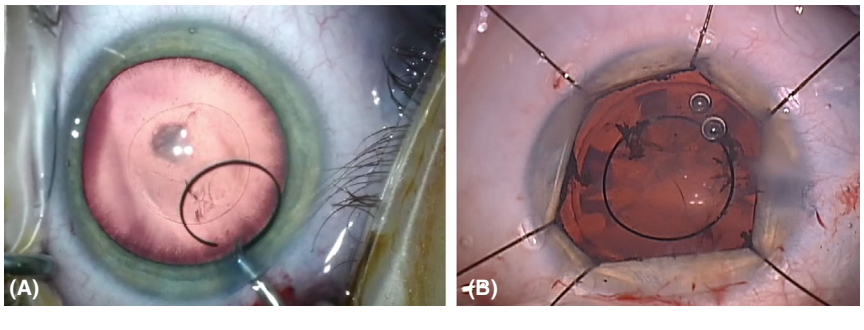

Fig. 6. Damage of the caliper ring during its explantation with the risk of endothelial trauma (A). Age at surgery 2.7 months. B – iris retractors in case of insufficient pharmacological dilation of the pupil. Age at surgery 10 months.

Management of early postoperative complications

Iris capture with posterior synechia was noticed in 2 of 39 cases (5.1%) of the entire cohort. In one case, the iris capture was partial, and in one case it was circular. In the case with partial iris capture, the pupil was dilated with mydriacyl 1% eye drops and then constricted with pilocarpin 1%. In the case of circular iris capture, a repeated surgical release of the synechia and the iris capture was needed (Fig. 3).

Visual axis re-opacification (VAR) was noticed in 2 of 39 cases (5.1%); either it was caused by improper implantation of the bag-in-the-lens IOL or postoperative dislocation of the posterior capsulorhexis edge from the IOL groove. It allowed the capsular epithelial cells to escape the incompletely closed space of the capsular bag, proliferate onto anterior vitreous and obscure the IOL optic. In these cases, a surgical treatment with pars plana vitrectomy was applied (Video S3). Once the re-opacification and vitreous were removed, the free dislocated edge of the PCCC was identified and re-implanted into the IOL groove. No further re-opacification was noted thereafter.

Bag-in-the-lens IOL dislocation in the vitreous cavity was noted in 1 of 39 cases (2.6%) (Fig. 7). It occurred apparently due to too large ACCC and PCCC. In the video-documented case, a pars plana vitrectomy was performed and then an attempt was made to re-implant the bag-in-the-lens IOL. However, as the IOL was unstable, we decided to remove it and implanted a sulcus fixated three-piece IOL.

Precipitates of *the bag-in-the-lens IOL optic* occurred in 2 of 39 cases (5.1%) during the early postoperative period. It was noticed in cases with preoperative posterior synechia as superficial cellular precipitates on the anterior or/and posterior bag-in-the-lens IOL surface (Fig. 8). No treatment was needed as the precipitates were considered not to be optically significant.

Discussion

Bag-in-the-lens IOL implantation technique which was first described by Tassignon et al. 2002; is an alternative surgical approach for cataract treatment in children and adults. Over the last decade, this technique was reported to have very promising postoperative results in children reducing the rate of posterior lens opacities (Tassignon et al. 2007, Van Looveren et al. 2015; Nyström et al. 2018).

The visual outcomes after paediatric cataract surgery with the bag-in-the-lens technique are strongly related to surgical complications that can happen either during the surgery or in the postoperative period. Intra- and postoperative problems are typical to all kinds of cataract surgery with or without implantation of intraocular lenses and in all age groups. It has been shown that the concept of bag-in-the-lens technique decreases the number of postoperative complications, such as posterior capsule opacification or macular oedema. Some of the complications occur because of intraoperative manipulations, other complications are related to the anatomical and physiological characteristics of the developing paediatric eye. Among them are the small size of the anterior chamber, underdevelopment of the anterior chamber angle, short axial length, more active tissue response on surgical intervention and more. There is a number of publications dedicated to bag-in-the-lens IOL in children that describe the visual outcomes and the complication rate. However, there is a lack of information regarding the prevalence of age-dependent complications as well as the management of complications. To the best of our knowledge, this is the first detailed report of intra- and early postoperative complications related particularly to bag-in-the-lens IOL implantation technique in children of different age groups. Additionally, we describe the management of the typical complications related to bag-in-the-lens IOL implantation. This should be helpful when new surgeons want to adopt the bag-in-the-lens IOL technique in the paediatric age group.

In 2002, Tassignon et al. (2002) first published the use of bag-in-the-lens technique *in vivo* in a group of nine patients (10 eyes), including a case with bilateral cataract in a 4-year-old girl. After this first bag-in-the-lens IOL implantation in a child, the authors reported that in 22 months of follow-up there were no complications in the anterior and posterior eye segment, the IOL remained well-centred and visual acuity was 0.6 (decimal) on both eyes. In 2007, Tassignon et al. (2007) published the results of a first case series of bag-in-the-lens technique in 34 eyes of 22 children of different age (2 months–14 years). Among intraoperative complications, the authors reported the difficulties during bag-in-the-lens IOL implantation in four eyes: in three of them only the anterior capsule was inserted into the bag-in-the-lens IOL groove, and in one case the IOL was implanted in the sulcus due to microphthalmus and small anterior chamber diameter. In 4 eyes with persistent fetal vasculature (PFV) an anterior vitrectomy during the surgery was performed. In one eye at 1 week postoperatively, a dropped IOL occurred due to oversized ACCC and PCCC. Secondary pars plana vitrectomy was performed in one patient 3 months after the surgery with VAR. During the surgery, the dislocated posterior capsule was re-implanted into the IOL groove. Additionally, the authors reported one case of iris capture corrected with second surgery, and two glaucoma cases postoperatively, treated with surgery and eye drops. In our cohort, initially both capsulorhexes

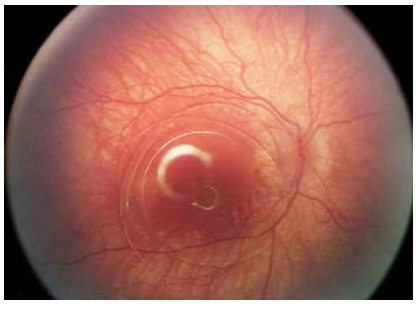

Fig. 7. Dislocation of bag-in-the-lens IOL into the vitreous cavity due to inadequate size of capsulorhexes. Age at surgery 3.8 months.

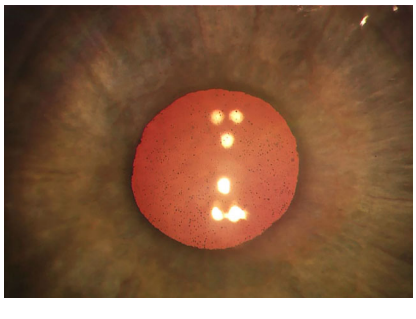

Fig. 8. Cellular precipitates onto the anterior and posterior IOL surface in the early postoperative period. Age at surgery 10 months

were implanted into the bag-in-the-lens IOL groove in all cases. We did not perform a sulcus implantation of bag-in-the-lens IOL. The rate of anterior vitrectomy was, however, higher in our series, which was associated with either posterior capsule or anterior vitreous changes. Postoperatively we experienced only one case of bag-in-the-lens IOL dislocation into the vitreous cavity associated with oversized ACCC and PCCC (Table 3). In this case, after pars plana vitrectomy, the bag-in-the-lens IOL was exchanged to a sulcus fixated IOL. Iris capture occurred in our cohort in two cases (2.2%) in the early postoperative period. Ocular hypertension was diagnosed in seven cases (7.8%) after the surgery, and treated with eye drops. Two cases (2.2%) of secondary postoperative glaucoma required surgical treatment.

Van Looveren et al. (2015) (Tassignon group) published the results after 5 years follow-up results of bag-in-the-lens in in 46 paediatric eyes operated between 2 months and 14 years of age with an overall clear visual axis in 91.3%. They reported VAR in four eyes of three patients, who were treated with anterior vitrectomy and re-implantation of the posterior capsule into the bag-in-the-lens IOL groove. Three cases of this subgroup were diagnosed in children younger than 6 months at the time of the surgery. Glaucoma was reported in one case 1 year after the surgery which necessitated surgical treatment (Baerveldt valve implantation). However, the IOP values were not indicated. Additionally, the authors reported two cases with anterior peripheral synechia, who underwent surgical correction. In our cohort, we observed two cases (2.2%) with anterior peripheral synechia, who necessitated secondary surgical intervention.

In 2018, Nyström et al. (2018) published the results of 109 eyes of 84 children aged from 2 weeks to 14.1 years, including 24 eyes of 16 children aged ≤6 weeks, with a median follow-up period of 2.8 years (range 7 months–5.8 years). A clear visual axis was reported in 95.4% of cases. Among postoperative complications were five eyes (4.6%) with visual axis opacification. Glaucoma was reported in 15 eyes (13.8%) and ocular hypertension, that required pharmacologic IOP-lowering was documented in five cases (4.6%). Additionally, in eight cases (7.3%) IOL-luxation was described, and in three cases (2.8%) an IOL-exchange and in two cases (1.8%) an IOL explantation were performed. The reasons for IOL-exchange were calcification of the anterior surface of bag-in-the-lens IOL (one case), myopization due to glaucoma (one case) and IOL luxation into the vitreous (one case). A chronic iritis and bag-in-the-lens IOL luxation were the indication for IOL explantation in two cases.

Van Looveren et al. (2015) reported on the incidence of secondary glaucoma in paediatric cataract with primary implantation of bag-in-the-lens IOL and detected one case of glaucoma (2.2%) during a 5-year follow-up. Nyström et al. (2018) described secondary glaucoma in 15 eyes (13.8%) and ocular hypertension in five cases (4.6%). In our cohort, we observed in the early postoperative period secondary glaucoma in two cases (2.2%) and intraocular hypertension in seven cases (7.8%). The rate of secondary glaucoma after cataract surgery in children was reported to be 13% and 19% (Knight-Nanan et al. 1996; Kirwan et al. 2010; Plager et al. 2014).

There is no unique approach to diagnose postoperative intraocular hypertension and secondary glaucoma in patients operated for infantile cataract. Additionally, the variety of aetiological factors that lead to intraocular pressure (IOP) increase in the postoperative period of different age groups is diverse. The maximal IOP value considered to be a sign of secondary glaucoma and morphological signs differ in different reports as well. Moreover, the measurement technique is also not standardized and the IOP bias caused by general anaesthesia is usually not taken into consideration. For example, Tassignon et al. (2007) considered IOP increase ≥20 mmHg to be glaucomatous change. Van Looveren et al. (2015) in long term follow-up after bag-in-the-lens IOL implantation in children reported one case of postoperative glaucoma, but the IOP values were not reported. Nyström et al. (2018) in their report defined glaucoma as an IOP ≥ 22 mmHg and buphthalmus, enlarged cornea, corneal oedema, glaucomatous appearance of the optic disc, a myopic shift or an increase of axial length more than predicted based on individual growth curves (Zetterberg et al. 2015). In our cohort, we defined postoperative intraocular hypertension as IOP ≥ 12 mmHg measured with applanation tonometry Perkins Tonometer Mk2 (Haag-Streit, Essex, UK) in general anaesthesia or as IOP ≥ 20 mmHg with iCare® PRO (Model: TA03, iCare Finland Oy, Vantaa, Finland) in the awake state, and secondary glaucoma – according to Nyström et al. (2018) which was described above.

Kahn & Dodick (2012) reported a comparative study of IOL optic surface damage in high-powered hydrophilic acrylic IOLs injected through small cartridge injector systems depending on its temperature before the injection (Kahn & Dodick 2012). The authors reported the presence of optic surface abnormalities such as debris, microscratches or microcracks in 50% of implanted IOL and concluded that prewarming of high-powered acrylic IOLs up to 45°C can reduce the IOL defects. Another study showed that a manufacturer-supplied hexagonal nozzle injector has caused linear scratches on the posterior surface of the hydrophilic acrylic IOL (Harsum et al. 2010). In our cohort, we used a 2.2-mm manufacturer-supplied cartridge injection system (Medicel AG, Thal, Switzerland) for hydrophilic acrylic bag-in-the-lens IOL implantation, and observed two cases of IOL damage (one case with scratches, one case with IOL break during reimplantation (Video S4). The mean pre-warming of high-powered bag-in-the-lens IOL before injection using small cartridge injector systems in paediatric cataract surgery has to be considered.

In our case series in eyes with small pupil, we used flexible iris retractors for mechanical mydriasis. Local stretching of the iris with iris retractors led to the damage of rim pigment. Alternatively, different kinds of iris retracting devices with smooth dilation principle can be used (Malyugin 2017). But the application of iris expanders is limited in the youngest children due to the small size of their eyes (anterior chamber depth, white-to-white distance, etc.).

The use of pars plana vitrectomy in complicated cases of bag-in-the-lens IOL implantation in children was previously reported (Tassignon et al. 2007; Van Looveren et al. 2015; Nyström et al. 2018). In our cohort,

we used only transcorneal vitrectomy, as we believe that this approach is minimally invasive, it can decrease the risk of retinal complication and is sufficient to deal with prolapsed vitreous or PFV.

The range of bag-in-the-lens IOL types available from the Morcher company includes 89D Type that was developed for small eyes (AL < 18.0 mm) and/or small white-to-white distance (<10.0 mm) with total diameter 6.5 mm and optic diameter 4.5 mm (http://www.morcher.com/nc/en/products/foldable-iols.html Assessed on 28 Jun 2019). In our cohort, we did not implant IOL 89D Type because we considered that the 4.5 diameter optic could be too small for the optic system of the growing eye in the future.

Dhubhghaill et al. (2015) from the Tassignon group reported a case of bag-in-the-lens IOL opacification 11 years after the implantation. Analysis of the explanted bag-in-the-lens IOL displayed a deep granular opacification consisting predominantly of calcium and phosphates. A new bag-in-the-lens IOL was implanted in this case instead. In our cohort, we did not observe changes or opacifications of the IOL material but the mean postoperative follow-up is still relatively short. The only changes of bag-in-the-lens IOL were the cellular precipitates (presumably pigmented cells) onto the anterior and posterior IOL surface already in the early postoperative period (Fig. 8).

A limitation of the present study is that the surgeries were performed by two subsequent surgeons, who have learned the bag-in-the-lens technique in their unique way. The learning curve of both surgeons was different and complications rate as well. Another limitation is the unequal number of eyes in each age group, which could influence the conclusions. As paediatric cataract is a relatively rare condition and the number of clinics in Germany dealing with this pathology is high, it was difficult to enrol the same number of patients in each age group. The fact that only 39 cases out of 90 cases were video documented is also a limitation, as the management of some complications occurring in the 51 cases between 2008 and 2015 may not have been described in detail.

In summary, the study demonstrates the efficacy of bag-in-the-lens IOL implantation technique in different paediatric age groups. In spite the learning curve, which can take between 40 and 50 cases, and existing intra- and postoperative complications, the rate of postoperative VAR after bag-in-the-lens IOL implantation is considerably lower compared to the reports of traditional lens-in-the-bag technique in paediatric cataract cases. Visual axis reo-pacification (VAR) as one of the most crucial postoperative complications with regard to amblyopia was documented in 5 of 90 cases (5.6%), with a success rate in 85 of 90 cases (94.4%). The rate of intra- or postoperative complications in our cohort does not present considerable differences compared to previously published studies with bag-in-the-lens IOL technique in children. Knowledge about the management of intra- or postoperative complication specifically related to bag-in-the-lens IOL implantation should be useful to shorten the learning curve. However, because of the variability of pathological changes of the eyes with paediatric cataract, the rate of complications can vary in different age groups.

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Correspondence:
Lyubomyr M. Lytvynchuk MD, PhD
Department of Ophthalmology
Justus-Liebig-University Giessen
University Hospital Giessen and Marburg GmbH
Campus Giessen, Friedrichstrasse 18, 35392 Giessen
Germany
Tel: +4964198543820
Fax: +4964198543809
Email:
Lyubomyr.Lytvynchuk@augen.med.uni-giessen.de

Source of public support: Department of Ophthalmology, Justus-Liebig-University Giessen, Friedrichstrasse 18, 35392, Giessen, Germany Phone +4964198543820 Fax +4964198543809.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. Conventional bag-in-the-lens IOL implantation technique in a case of congenital cataract operated at the age of 10 months.

Video S2. Pars plana vitrectomy for removal of the VAR that occurred due to incomplete insertion of the posterior capsule into the IOL groove. Age at surgery 2 years.

Video S3. Standard proof of the correct position of the implanted bag-in-the-lens IOL by gently moving the IOL in four directions in the horizontal plane in order to visualize complete implantation of both capsules in the groove over 360°. Age at surgery 1 year.

Video S4. Damage of the bag-in-the-lens IOL during second attempt of implantation after first failed attempt. Age at surgery 1.5 years.