



Pediatric bag-in-the-lens intraocular lens implantation: Long-term follow-up

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PURPOSE: To evaluate long-term follow-up results of pediatric cataract surgery using the bag-in-the-lens (BIL) intraocular lens (IOL) implantation technique.

SETTING: Antwerp University Hospital, Edegem, Antwerp, Belgium.

DESIGN: Prospective case series.

METHODS: All pediatric cataract surgeries with BIL IOL implantation performed at the Antwerp University Hospital were evaluated. Only cases that completed a follow-up of 5 years at the hospital's Department of Ophthalmology were included in this study.

RESULTS: Forty-six eyes of 31 children had a complete follow-up of 5 years or more after BIL IOL implantation. Sixteen cases were unilateral and 15 were bilateral. Patient age at time of surgery ranged from 2 months to 14 years. The mean refraction at the end of follow-up was -1.99 diopters (D) ± 3.70 (SD). In bilateral cases, a corrected distance visual acuity (CDVA) of better than 0.5 was attained in 86.7% and a CDVA of 1.0 was achieved in 56.7%. In unilateral cases, 31.2% achieved a CDVA of better than 0.5 but none obtained a CDVA of 1.0. A clear visual axis was maintained in 91.3% of cases during follow-up. Visual axis reopacification was detected in 4 eyes of 3 cases, all due to inadequate BIL IOL positioning. None of these eyes needed more than 1 intervention to maintain visual axis clarity. Other than 1 case of glaucoma, no severe complications were detected.

CONCLUSION: Long-term follow-up results show that BIL IOL implantation is a safe, well-tolerated approach for treating pediatric cataract with a very low rate of visual axis reopacification and a low rate of secondary interventions for other postoperative complications.

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Congenital cataract is the most common potentially reversible cause of childhood blindness.¹ The treatment of cataract in this population has long been known to pose difficulties beyond that of adult surgery.² The anatomy is naturally smaller with a shorter axial length (AL) and steeper corneal curvature, and although the lens itself typically is removed easily by aspiration, the increased elasticity of the capsular bag makes performing a capsulorhexis (anterior or posterior) more unpredictable. The timing and target refraction of implanted intraocular lenses (IOLs) and

postoperative refractive correction are still controversial, particularly in patients under 6 months old.^{3,4} Despite these difficulties, the main causes of a postoperative decline in vision are posterior capsule opacification (PCO) and visual axis reopacification. If the posterior capsule is left intact at time of surgery, PCO occurs in up to 80% of cases.⁵ Therefore, performing a primary posterior capsulotomy is now a standard approach in pediatric cataract surgery. This additional surgical step significantly reduces the rate of visual axis reopacification but does not eliminate

it because up to 40% of patients will experience partial or complete closure.⁶⁻⁹ In vitro evidence supports this observation by showing that lens epithelial cells (LECs) retain the capacity to proliferate even in the absence of a capsular scaffold.¹⁰ For this reason, an anterior vitrectomy is often routinely performed in pediatric cataract surgery and is advocated for preschool children.⁹

The bag-in-the-lens (BIL) technique is an advance in IOL design that addresses the persisting risk for visual axis reopacification. When using this technique, it is preferable that the primary posterior continuous curvilinear capsulorhexis (PCCC) be the same size as the anterior capsulorhexis. When correctly placed, the IOL is supported by the anterior and posterior capsular blades, which tightly encircle the IOL optic in the circumferential interhaptic groove.¹¹ By apposing the anterior and posterior capsules, the IOL design creates a seal that prevents LECs from migrating to the anterior vitreous.¹² Using this approach, we were able to minimize the need for an anterior vitrectomy, even in children younger than 2 years.¹³ Only in cases presenting with vitreous prolapse due to an abnormal vitreolenticular interface or in cases with persistent fetal vasculature (PFV) does an anterior vitrectomy remain necessary. The BIL concept was originally validated in the adult population.¹¹ Based on its success in adults, the BIL IOL was implanted in pediatric eyes and a prospective case series was commenced.¹³ At that time, all patients showed a clear visual axis immediately postoperatively and visual clarity was maintained in 93.8% of patients over the follow-up period. Failure to prevent visual axis reopacification was caused by inadequate BIL IOL positioning.

In this study, we expand on the original report and describe the results of a long-term (5-year follow-up) prospective study including the rate of complications and visual axis reopacification associated with the BIL technique and minimum use of anterior vitrectomy.

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PATIENTS AND METHODS

All pediatric cataract surgeries using the BIL implantation technique at the Antwerp University Hospital from July 01, 1999, to September 30, 2007, were registered in a database. The study was approved by the Ethics Committee of the University of Antwerp (EC 1/47/136) and adhered to the tenets of the Declaration of Helsinki.

A wide range of cataract types was treated, including nuclear fetal cataract, spherophakia, and cases with PFV. All surgeries were performed by the same surgeon (M.J.T.). None of the cataract surgeries were combined with other ocular interventions.

Biometry was performed immediately preoperatively under general anesthesia, and keratometry was based on measurements with a handheld keratometer (Retinomax, Righton). The ALs were based on A-scan echography (Pacscan 300A, Sonomed Escalon). The SRK/T formula¹⁴ was used for IOL calculation in all cases. Based on experiences with adult patients, eyes with an AL of less than 21.5 mm and more than 26.0 mm do not adhere well to the prediction formulas and were therefore considered outliers. This was compensated for by adding 0.5 diopter (D) to the calculation for every millimeter above or below these limits. Emmetropia was the target refraction in most cases. In younger infants, the target refraction was +3.0 D up to the age of 3 months, +2.0 D up to the age of 6 months, and +1.0 D up to the age of 9 months in cases of bilateral cataract. In cases of unilateral cataract, the calculation was also influenced by the refraction in the contralateral eye. The BIL IOL diopter power available in the operating room was up to 39.0 D.

The standard postoperative topical medication regimen required the use of an antibiotic drop and a prednisolone drop 4 times a day for 1 week and topical diclofenac sodium 4 times a day for 1 month. Postoperative visual training programs started the day after surgery and were reinforced in children with unilateral cataract.

Age at time of surgery, follow-up time, refraction, corrected distance visual acuity (CDVA), and postoperative complications were recorded in a database. Only cases that completed a follow-up time of at least 5 years at Antwerp University Hospital were included in this study. The detection of adverse events was based on clinical assessment over the course of follow-up. Patients whose follow-up data were incomplete were eliminated from the analysis.

RESULTS

One hundred thirty-three consecutive eyes of 107 children having pediatric cataract surgery performed at the Antwerp University Hospital during the study period were registered in a database. In all cases, BIL IOL implantation was feasible. Only 46 eyes of 31 children (13 girls and 18 boys) completed at least a 5-year follow-up at the department and were included in this study. Sixteen of these cases were unilateral and 15 were bilateral. Persistent fetal vasculature was present in 4 of the unilateral cases, and anterior vitrectomy was routinely performed only in these cases. The age at the time of primary surgery ranged from 2 months to 14 years, with a mean of 6 years. Eleven of the reported cases were performed on 7 children younger

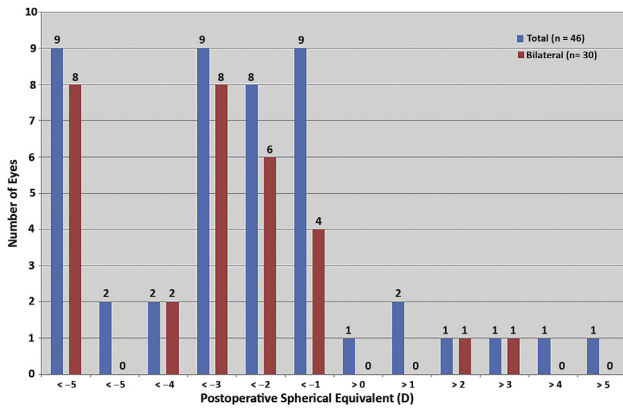


Figure 1. Five-year postoperative SE results.

than 1 year. The mean age of the unilateral cases was 55 months ± 45 (SD) (range 5 to 171 months) and of the bilateral cases, 87 ± 65 months (range 2 to 170 months). The follow-up ranged from 60 months to 157 months, with a mean follow-up of 78 months.

Postoperative Refraction and Spherical Equivalent

Refractive outcomes showed a distribution with a tendency toward mild myopia. A high myopic refraction of more than -6.00 D was found in 4 (8.7%) of the 46 eyes. The mean refraction was -1.99 ± 3.70 D, and 24 of 46 cases (52%) achieved a spherical equivalent (SE) within -2.0 to +2.0 D (Figure 1).

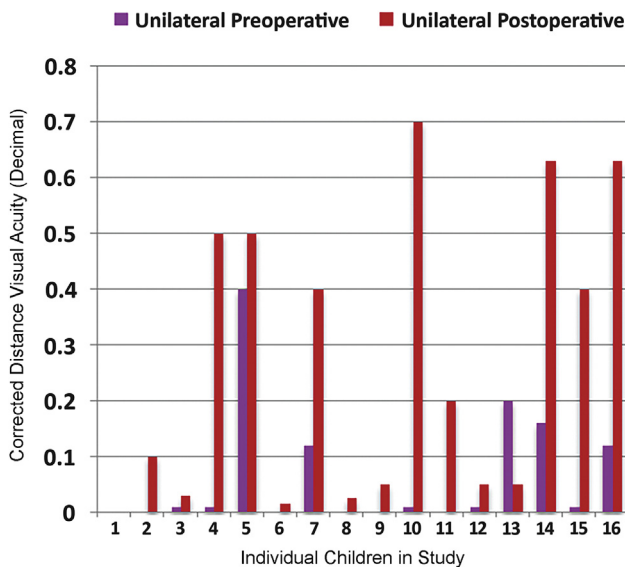


Figure 3. Visual acuity results in unilateral BIL IOL surgery (x-axis= number of each individual child included in the study; y-axis= CDVA in decimal notation).

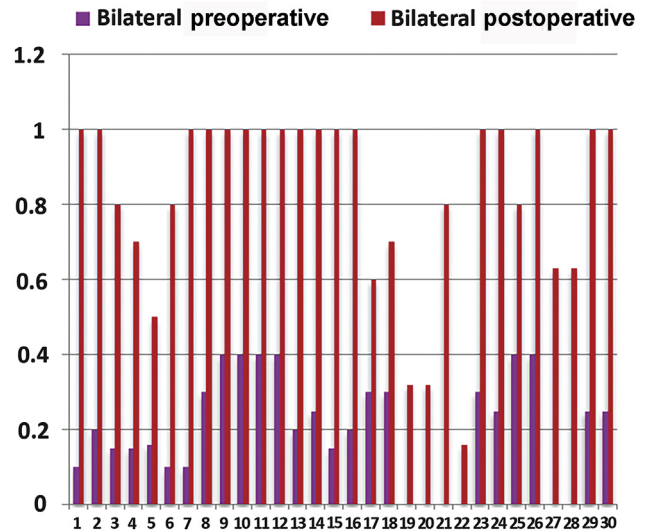


Figure 2. Visual acuity results in bilateral BIL IOL surgery (x-axis= number of each individual child included in the study; y-axis= CDVA in decimal notation).

Postoperative Corrected Distance Visual Acuity

In some cases, the CDVA could not be recorded preoperatively, either because of the young age of the patient or because the density of the cataract decreased vision to below recordable levels. Fifteen children (30 eyes) who had bilateral surgery showed significant improvement, moving from a preoperative mean CDVA of 0.2 (range 0.0 to 0.4) to a postoperative mean CDVA of 0.83 (range 0.2 to 1.0) (Figure 2). A CDVA better than 0.5 was attained in 26 (86.7%) of 30 cases and a CDVA of 1.0 was achieved in 17 (56.7%) of 30 cases.

Sixteen children who had unilateral surgery showed a range of improvement from a preoperative mean CDVA of 0.07 (range 0.0 to 0.4) to a postoperative mean CDVA of 0.27 (range 0.0 to 0.7) (Figure 3). The unilateral cases had poorer preoperative CDVAs than bilateral cases; 5 unilateral cases (31.2%) achieved a postoperative CDVA of 0.5 or better, but none achieved a postoperative CDVA of 1.0.

Complications

Several complications were encountered during the follow-up period. Visual axis reopacification was detected in 4 eyes of 3 children over the total follow-up period, resulting in 42 (91.3%) of 46 eyes maintaining a clear visual axis over 5 years after primary surgery (Figure 4). The first case of visual axis reopacification occurred in a child who initially presented at 5 months of age with a white cataract and PFV. A cataract extraction, PCCC, and anterior vitrectomy were performed, but reliable positioning of the posterior capsule within

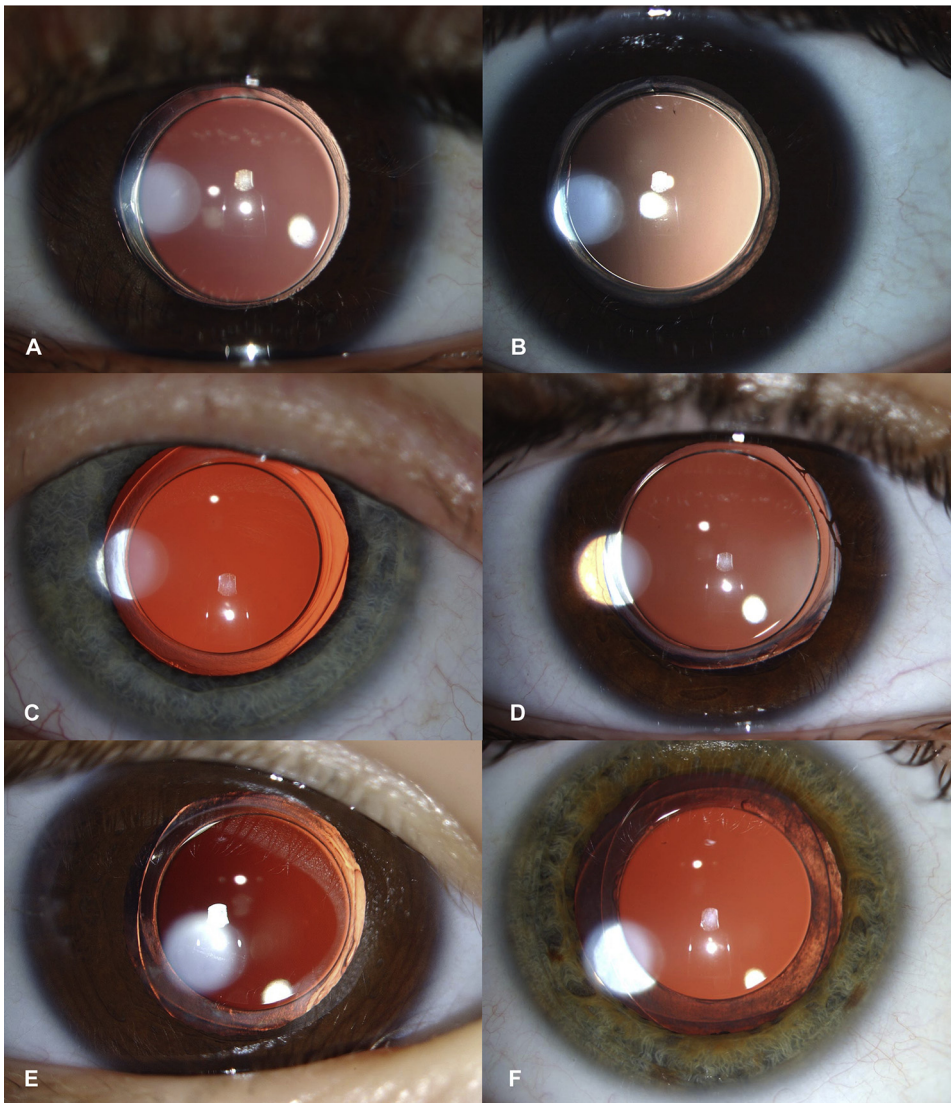


Figure 4. Images of BIL IOL during follow-up after implantation. *A:* Nine years after surgery performed at 4 years of age. *B:* Ten years after surgery performed at 4 years of age. *C:* Seven years after surgery performed at 6 years of age. *D:* Nine years after surgery performed at 3 years of age. *E:* Ten years after surgery performed at 7 months of age. *F:* Six years after surgery performed at 7 years of age.

the interhaptic groove of the BIL IOL was not possible at the time of primary surgery. Four months later, the child had visual axis reopacification that required cleaning the visual axis and repositioning the IOL.

The second case involved apparently uneventful BIL IOL implantations in both eyes at 3 years of age. Visual axis reopacification developed in the right eye only, 8 years later (Figure 5). The second surgical intervention consisted of an IOL exchange and an anterior vitrectomy. Intraoperatively, it was found that the posterior capsule was partially out of the BIL groove, allowing the LECs access to the anterior hyaloid space. The third child developed bilateral visual axis reopacification. The primary surgery had been performed at 3 months of age and had been complicated by pupil miosis. The restricted view impaired the correct positioning of the anterior and posterior capsular blades

in the interhaptic groove of the BIL IOL, allowing LECs to proliferate. Secondary surgery was required in the left eye 5 months later and in the right eye 10 months later. None of the eyes that developed visual axis reopacification needed more than 1 reoperation to maintain visual axis clarity.

One case of glaucoma was detected in this series. This patient initially presented at 5 months of age with a white cataract associated with severe PFV. At the 1-year follow-up visit, increased intraocular pressure (IOP) was noted. Despite Baerveldt valve implantation supplemented with cyclophotocoagulation to stabilize the IOP, visual function was lost in this eye.

In 2 eyes, anterior peripheral synechiae formed at the corneal incision site, inducing corectopia and requiring lysis 1 month postoperatively. No cases of posterior synechiae were seen.

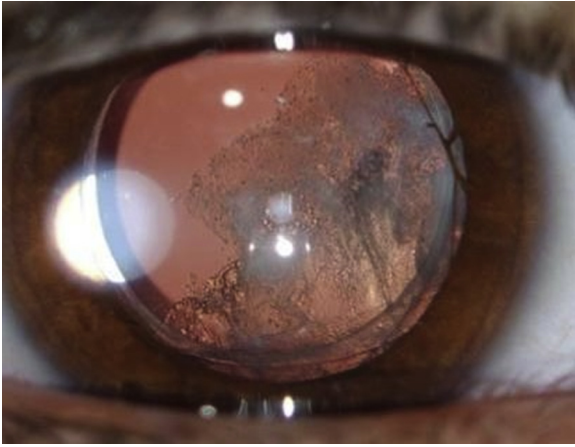


Figure 5. Image of visual axis reopacification after BIL IOL implantation.

No cases of IOL decentration, iris chafing, or other severe complications, such as uveitis, endophthalmitis, or retinal detachment, were encountered.

Patients Younger Than 6 Months at the Time of Cataract Surgery

Five children (8 eyes; 2 unilateral cases, 3 bilateral cases) were 6 months or younger at the time of surgery. In this small group, 3 eyes had no adverse events, 3 eyes needed 1 additional surgery for visual axis reopacification, 1 eye required lysis of anterior synechiae, and 1 eye presented severe PFV and lost visual function due to glaucoma. The mean CDVA at the end of follow-up in this group was 0.32 (range 0.0 to 0.8), with 2 eyes having a final CDVA of 0.1 or less.

DISCUSSION

The BIL IOL implantation technique has been safe and effective in adult patients for many years.¹¹ Short-term results published in 2007¹³ confirm that the BIL technique can also be successfully used in the pediatric patient population, but until the present study, no long-term follow-up results of this technique were available for this young group of cataract patients. For these young patients, the BIL IOL implantation technique offers a major advantage by providing a continuous and maintained clear visual axis in the majority of cases during the crucial years of eye development.

Bag-in-the-lens implantation is sometimes believed to be too difficult as a surgical technique because it requires a calibrated anterior and posterior capsulorhexis. Especially in children, sizing the capsulorhexis can be challenging, but in our experience BIL IOL implantation was feasible in all 133 consecutive pediatric cataract surgeries recorded during the study dates. The introduction of femtosecond laser-assisted

capsulectomy will probably further facilitate the surgical step of capsulorhexis, and sizing will be even more precise.

One of the most significant complications after pediatric cataract surgery is visual axis reopacification, which might interfere with postoperative visual rehabilitation and can induce deprivation amblyopia. To decrease the risk for visual axis reopacification, an anterior vitrectomy often is routinely performed in pediatric cataract surgery and is advocated for infants and babies.^{9,15} Unfortunately, removing the anterior hyaloid membrane as scaffold for LEC proliferation will not eradicate visual axis reopacification.^{9,16} If no PFV or peroperative vitreous prolapse is present, an anterior vitrectomy is not indicated when using the BIL IOL implantation technique, not even in infants and babies. The tight fusing of both capsular blades in the interhaptic groove of the BIL IOL prevents LECs from escaping from the capsular bag and proliferating and ultimately explains the low rate of visual axis reopacification after successful BIL IOL implantation. The anterior vitreous membrane should be kept intact, if possible, because it acts as a major barrier between the anterior and posterior segments of the eye.¹⁷

In this study, a clear visual axis was found in 91.3% of cases (42 of 46 eyes) over the 5 years after primary surgery. Three of the 4 cases that developed visual axis reopacification were in infants aged 6 months or younger at the time of surgery. When BIL IOL implantation was performed in children older than 6 months, 97.4% of eyes (37 of 38) maintained a clear visual axis throughout the study. All 4 cases of visual axis reopacification occurred because intraoperative factors prevented the proper positioning of the posterior capsule in the interhaptic groove of the BIL IOL. In all cases, only 1 additional surgery was required to restore visual axis clarity and position the capsular blades tightly within the BIL IOL.

Secondary glaucoma remains the most sight-threatening long-term complication after cataract surgery in pediatric eyes. The reported incidence varies widely, although the risk is higher when the child is younger at the time of surgery, when cataracts are associated with other anterior segment anomalies, and in eyes that have been left aphakic.¹⁸⁻²⁰ It has been suggested that primary IOL implantation might reduce the risk for postoperative glaucoma, but this is still controversial.²¹ Early surgery, in patients younger than 9 months, was associated with a 7.2-fold increased risk for glaucoma; furthermore, the onset of glaucoma was observed up to 10 years after surgery.²² The presence of PFV increases the risk for glaucoma by a factor of 3.1.¹⁸ In our series, 1 eye developed secondary glaucoma and required surgery. In that case, the cataract surgery was performed at

5 months of age and was associated with severe PFV. No other patient in our study required surgical or medical glaucoma treatment.

Postoperative inflammation is also a particular concern in the pediatric cataract cohort. Children are prone to more aggressive anterior chamber inflammation than adults, which predisposes them to posterior synechiae, visual axis reopacification, and macular edema. Several intraoperative surgical interventions, such as intraocular enoxaparin, have been proposed to minimize these reactions,²³ although these results have not been confirmed.²⁴ The use of an intraoperative intracameral triamcinolone injection or postoperative oral prednisolone has been suggested for surgeries involving congenital cataracts.^{25,26} Our postoperative antiinflammatory regimen was similar to that for adult cataract surgery and included only topical corticosteroids and nonsteroidal topical antiinflammatory drops, both administered 4 times a day for a total of 1 month postoperatively. Unlike the infant aphakia treatment study drops protocol,¹⁵ atropine drops were not used because a small pupil is preferable for preventing early postoperative BIL IOL incarceration in the iris margin. In our series, anterior synechiae were found at the incision site in eyes of 2 children, caused by an early postoperative inflammatory response or an unstable incision closure. A surgical lysis was performed in both cases; there were no further inflammatory complications. This low rate of postoperative inflammation and low regimen of postoperative medication needed in these young eyes might be because the BIL IOL seals off the remaining LECs from the aqueous humor, decreasing their contribution to inflammatory reactions. Also, with the BIL IOL design, the haptics are suspended centrally by the bag and have no direct mechanical contact with the ciliary body or sulcus.

The Infant Aphakia Treatment Study group²⁷ recently reported the results in a 5-year follow-up of IOL implantation during primary surgery in infants with unilateral cataract. That study included a standard lens-in-the-bag IOL procedure only. Comparing those results with the present study's 5-year follow-up results of unilateral BIL IOL implantation in infants can only be anecdotal because our study only included 8 eyes of 5 children younger than 6 months, of which only 2 were unilateral cases.

Currently, there is no consensus on the ideal postoperative target refraction in infants and children after cataract surgery, and IOL power calculations for very young eyes can be particularly challenging. This is primarily due to inaccuracies in the measurement of AL and of corneal curvature being more common because these parameters are measured in less-than-optimum conditions,^{3,28,29} but it also is because all IOL

calculation formulas have a higher error rate when used for small eyes. There is no preferred calculation formula for children because all formulas perform equally well in terms of IOL predictability.³⁰ Because we routinely use the SRK/T formula¹⁴ in our adult cataract population, we also use it in our pediatric cases. The SRK/T¹⁴ and the Holladay 1³¹ formulas appear to give good results and have equal predictive ability.³² In this cohort, the mean refraction after 5 years of follow-up was -1.99 ± 3.70 D and 52% of cases achieved an SE within 2.0 D of emmetropia. All refractive errors could be addressed with spectacles or contact lenses. No refractive surgeries were performed during the follow-up period. These results indicate that BIL IOL implantation and the IOL power calculation used give acceptable refractive results after 5 years of follow-up. Should a high refractive error develop later in life, many correction options are currently available, such as glasses, contact lenses, corneal refractive surgery, intraocular contact lenses, iris-fixated IOLs, sulcus-based IOLs, and BIL IOL exchange surgery.

A limitation of the present study is that only 46 of the 133 BIL IOL implantations were included. This was mainly because a complete follow-up of 5 years in our department was set as an inclusion criterion and most patients (often from East European countries) were referred back to their own ophthalmologist for follow-up. This study being monocentric also limits its value. We recommend the introduction of multicenter outcome registries of pediatric cataract surgeries to better understand the advantages and disadvantages of different techniques and approaches for cataract surgery in children.

The management of cataracts in children depends mainly on the potential for them to interfere with the child's visual development. Pediatric cataract cases have a high variability concerning surgical difficulty, complication rate, and visual prognosis. The BIL IOL implantation technique appears to be safe with low complication rates and as a result is our preference when surgery is indicated in children. In the majority of cases, it provides a clear visual axis for early visual rehabilitation of the child's eye.

Over the years, the visual prognosis after pediatric cataract has improved substantially. The final visual outcome depends on many factors, including the age of onset, whether it is unilateral or bilateral, the preexisting and coexisting ocular abnormalities, the timing of the surgery, the postoperative course and complications, and the adherence to amblyopia treatment.¹ In our series, a significant improvement in CDVA was obtained in all but 1 case (a PFV case complicated by glaucoma); however, as expected, there was a significant difference between the unilateral cases and bilateral cases.

The BIL IOL implantations in this study showed a very low rate of visual axis reopacification, a low rate of postoperative complications, and a low rate of secondary surgical interventions during the 5-year follow-up period. In addition, the surgical approach described reduces the need to perform a planned anterior vitrectomy except in cases complicated by PFV.

We can therefore conclude that BIL IOL implantation is a safe and well-tolerated approach for the treatment of pediatric cataract, with favorable visual outcomes and a low rate of visual axis reopacification and other complications.

WHAT WAS KNOWN

- The bag-in-the-lens implantation technique is safe and well tolerated in the pediatric population.
- When correctly positioned at the time of primary surgery, the edges of the capsulorhexis and the interhaptic groove form a tight seal, prohibiting proliferation of LECs outside the capsular bag. This way it prevents the occurrence of visual axis reopacification, a common complication of standard IOL implantation that can significantly impair visual rehabilitation in the critical early years.

WHAT THIS PAPER ADDS

- There was no need to perform an anterior vitrectomy in most pediatric cataract cases when using the BIL IOL implantation technique, even in infants.
- The BIL IOL implantation approach resulted in a low rate of visual axis reopacification and of other complications with subsequent low rates of reoperation.

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