Graefes Arch Clin Exp Ophthalmol (2013) 251:309–314
DOI 10.1007/s00417-012-1979-7

PEDIATRICS

Long-term outcome of primary versus secondary intraocular lens implantation after simultaneous removal of bilateral congenital cataract

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Received: 29 September 2011 / Revised: 1 February 2012 / Accepted: 20 February 2012 / Published online: 14 March 2012

Abstract
Background Long-term outcomes of intraocular lens (IOL) implantation for congenital cataract in children under 2 years old are still undetermined.
Methods We retrospectively reviewed all cases of bilateral congenital cataract who had undergone simultaneous bilateral cataract removal with posterior capsulotomy and central anterior vitrectomy between 1990 and 2010. Patients randomly underwent primary IOL implantation or secondary IOL implantation after a period of contact lens wear. The two groups were compared for visual outcome and complications during follow-up.
Results Cataract removal and primary IOL implantation was performed in 30 eyes (15 patients; nine males, six females) at a mean age of 6.8±4.2 months. After 79.31±63.4 months, best-corrected visual acuity (BCVA) was 0.53±0.36 EDTRS LogMAR. In 36 eyes (18 patients, 11 males, seven females) the lens was removed at a mean age of 5.42±2.80 months, and after 32.0±6.1 months of contact lens utilization, secondary IOL implantation was performed. After 109.0±33.8 months, BCVA was 0.54±0.4 ETDRS LogMAR. The association between age at surgery and final visual acuity and the difference between the two groups concerning type of cataract at baseline, BCVA and refractive error at last visit, incidence of posterior capsular opacification, glaucoma, strabismus, and nystagmus during follow-up were not significant ($p>0.05$). Myopic shift was more frequent in eyes undergone primary IOL implantation ($p<0.001$).
Conclusions Similar visual outcome and complications were observed during long-term follow-up after both primary and secondary IOL implantation following simultaneous bilateral congenital cataract removal with posterior capsulotomy and central anterior vitrectomy.

Keywords Posterior capsulotomy · Central anterior vitrectomy · IOL

The study was performed with informed consent, and following all the guidelines for experimental investigations required by the Institutional Review Board or Ethics Committee, to which all authors are affiliated.

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Introduction

In congenital cataract, the need for early intervention is well-established, to prevent visual deprivation and amblyopia [1]. Better understanding of the sensitive periods for the development and reversal of amblyopia has made it possible to optimize the timing of cataract removal, and improved surgical techniques [2]. In patients presenting with congenital cataract, the amblyogenic window for successful visual rehabilitation is probably up to only 12 to 16 weeks of age [3–6]. Spectacles [7, 8], contact lenses [9, 10], and intraocular lens (IOL) implantation [11–13] have been used for correction of surgical aphakia. Primary IOL implantation has become the preferred approach in children over 2 years old, but IOL implantation in children under 2 years remains controversial, as these eyes are more susceptible to myopic shift, intense posterior capsular opacification (PCO), and excessive uveal inflammations [14, 15]. Furthermore, the long-term outcomes of these implants remain undetermined. Herein, we compared the long-term visual outcome and complications of primary and secondary IOL implantation after removal of bilateral congenital cataract during the first 12 months of life.

Methods

In this retrospective study, we included children who were diagnosed as bilateral congenital cataract and operated on at the Pediatric Ophthalmology division of the Ophthalmology Department of the University Federico II of Naples between 1990 and 2010. Informed consent was obtained in accordance with IRB approval. Inclusion criteria were simultaneous surgery during first 12 months of life for bilateral congenital cataract, and primary or secondary IOL implantation. Congenital cataract was defined when patients younger than 6 months had cataract. Criteria for exclusion were non-simultaneous bilateral intervention, microphthalmos with a corneal diameter of less than 9 mm, co-existing organic ocular defects, retinopathy of prematurity, posterior-type persistent hyperplastic primary vitreous, persistent fetal vasculature, Down's syndrome, or systemic diseases able to influence learning ability. Prior to surgery, axial length was measured by an ultrasonic A-scan (Cinescan S Ophthalmic Ultrasound System, Quantel Medical S. A., Clermont-Ferrand, France). Initially, bilateral surgery was undertaken only when it was not safe to perform general anesthesia (one premature baby with convulsions, one premature baby with respiratory distress, one case with Down's syndrome, one case with respiratory distress, one case with patent ductus arteriosus, and one case with congenital rubella and patent ductus arteriosus). Afterwards, in consideration of the good results obtained in these cases, bilateral surgery was performed in the following cases with bilateral congenital cataract. In all cases, intraocular lens power was calculated with the Sanders–Retzlaff–Kraff II formula based on axial length and keratometry readings. The target IOL power (diopters, D) was selected after taking into consideration the predicted future growth of the eye and the consequent myopic shift. Hyperopic correction was targeted based on the age of the child at the time of surgery (+6 D if<6 months, +5 D from 6 to 12 months, +4 D from 1 to 2 years, +3 D from 2 to 4 years, +2 D from 4 to 6 years). These values were modified accordingly in case of a family history of high myopia or hyperopia. First implanted IOL were Pharmacia Heparin Surface Modified AC IOL Model 722 C. Subsequently, Acrysof MA60 BM IOL and, recently, Hoya AF-1 IOL were used. All operations were performed by the same experienced surgeon (A.M.) under general anesthesia. For simultaneous irrigation and aspiration of the lens, mechanical anterior capsulorhexis, manual or automized extracapsular lens extraction, posterior capsulorhexis or posterior capsulotomy and central anterior vitrectomy were performed. Antibiotics were postoperatively injected into the anterior chamber, and dexamethasone was injected subconjunctivally after surgery. Dexamethasone was injected subconjunctivally also during surgery in those cases whose postoperative home care was expected to be not completely safe. To reduce the risk of contamination from the first operated eye, a sterile surgical set and a complete change of surgical gown and gloves were used for the second eye. Patients randomly underwent primary implantation of the IOL at the time of lens removal, or secondary postponed implantation of the IOL after a period of contact lens use after lens removal. Primary IOL implantation was performed immediately after phacoaspiration. The goal was to implant the IOL in the bag. Secondary IOL implantation was performed as a distinct surgical access through corneal incision, 360° annular synechiotomy, posterior chamber IOL inserted in the ciliary sulcus, and 10-0 nylon suture. Following both primary and secondary IOL implantation, the operated eyes were treated with topical antibiotics, corticosteroids, and mydriatic and cycloplegic agents. Before and after surgery, the patients underwent a complete ophthalmological examination, including manifest or cycloplegic refraction, measurement of intraocular pressure (IOP) with Perkins applanation tonometer, strabismus examination with Krimsky test or alternative cover test, and Hirschberg test when necessary. Best-corrected visual acuity (BCVA) was measured after 4 years of age on a Snellen scale of 20/200 to 20/20, with the patient wearing optimal refractive correction. Visual acuities were converted to the logarithm of the minimum angle of resolution (Early Treatment Diabetic Retinopathy Study, ETDRS, LogMAR) for statistical analysis. Refraction was evaluated by skyascopy. The refractive error was calculated as the spherical equivalent refraction, using the algebraic power of the sphere plus half the cylindrical power. Cataract density was estimated by the degree of obstruction of the ocular fundus caused by the opacity during direct and indirect ophthalmoscopy. Cataracts that impeded the vision of the red reflex at ocular fundus examination were considered as total. Until they were 3 to 4 years old, the patients were examined every 4 months, and then until 7 to 8 years old, every 6 months. After 9 years of age, a yearly check-up was carried out. Patients who showed a BCVA difference of two or more Snellen lines between the two eyes were grouped as amblyopic patients, and received occlusion therapy. Statistical calculations were performed using the Statistical Package for Social Sciences (version 17.0, SPSS Inc., Chicago, IL, USA). Visual acuity data in both groups were compared by using the Kruskal–Wallis test. A logistic regression model was used to assess the influence of age at surgery and type of cataract on final BCVA, and the association between age at surgery and myopic shift. The chosen level of statistical significance was $p<0.05$.

Results

Among 813 patients with congenital monolateral or bilateral cataract operated between 1990 and 2010, a total of 33 patients were identified within the inclusion criteria. Details of patient demographics are listed in Table 1.

Table 1 Demographics of infants having bilateral congenital cataract surgery and primary or secondary intraocular lens (IOL) implantation

	Primary IOL implantation	Secondary IOL implantation	*P*
Number of eyes/patients	30/15	36/18	
Preoperative axial length (mm)	19.1±1.5	18.9±2.2	0.1
Age at surgery, months (range)	6.8±4.2 (2–12)	5.42±2.80 (2–12)	0.6
Time to secondary IOL implantation, months (range)	–	32.0±6.1(19-50)	–
Follow up, months (range)	79.31±63.4 (12–236)	109.0±33.8 (42–510)	0.4
Age at last visit, years (range)	7.4±6.2 (1.1–19.6)	7.35±2.9 (4.3–15.0)	0.9
BCVA at last visit (ETDRS LogMAR)	0.53±0.36	0.54±0.40	0.2
Refractive error at last visit (range)	−2.5±3 D (−8.25 to +2.00)	+0.4±2.3 (−7.50 to +2.50)	0.02

ETDRS, Early Treatment Diabetic Retinopathy Study; *p*, statistical significance between the two groups

Irrigation and aspiration of the lens and primary IOL implantation was performed in 30 eyes (15 patients, nine males, six females) at a mean age of 6.8±4.2 months (range 2–12 months). In this group, cataract was total in 18 eyes, and partial in 12 eyes, of which seven were dense zonular, three posterior polar and two posterior lenticonus. Strabismus was not present in any case before surgery, while nystagmus was present in 4/15 patients (26.6 %). The mean preoperative axial length was 19.1±1.5 mm. Mean power of the implanted IOL was 25.1±2.3D. IOL fixation was capsular bag in 22 eyes (73.3 %) and sulcus-sulcus in eight eyes (26.7 %). Pharmacia Heparin Surface Modified AC IOL Model 722 C were implanted in 12 eyes, Acrysof MA60 BM IOL were implanted in ten eyes and Hoya AF-1 IOL were implanted in eight eyes. Mean follow-up was 79.31± 63.4 months (range 12–236 months). During follow-up, in one case synechiotomy in combination with iridectomy was necessary due to ocular hypertension 16 years after cataract surgery, while in one case a multifocal IOL that had been inserted by a different Eye Service had to be bilaterally explanted and substituted with a monofocal IOL after 46 months. At last visit, the mean age was 7.4±6.2 years (range 1.1–19.6 years), and the mean refractive error was −2.5±3 D (range, −8.25 to +2.00). Myopic shift was present in eight eyes (26.6 %, four patients, aged mean 5.6±2.2 months at the time of intervention). Mean BCVA at last visit was 0.53±0.36 EDTRS LogMAR. Four eyes (13.3 %) presented a BCVA lower than 20/200, while BCVA was between 20/200 and 20/40 in nine eyes (30 %), and 20/40 or greater in seven eyes (23.3 %). Nystagmus was present in 3/15 patients (20 %). Strabismus developed during follow up in 6/15 patients (40%; exotropia in four cases, esotropia in two cases) (Table 2) and was operated in two cases, after 36 and 110 months. No cases of posterior capsular opacification were observed.

Removal of the lens and secondary IOL implantation was performed in 36 eyes (18 patients, 11 males, seven females). In this group, cataract was total in 24 eyes, and partial in 12 eyes, of which five were dense zonular, four posterior polar and three posterior lenticonus. Strabismus was not present in any case, while nystagmus was present in 7/18 patients (38.8 %). No significant differences were found with regard to type of cataract between the two groups ($p>0.05$). Preoperative axial length was 18.9±2.2 mm, and the power of the implanted IOL was 25.5±2.0D. Mean age at removal of lens was 5.42±2.80 months (range 2–12 months), while secondary IOL implantation was performed after 32.0± 6.1 months (range 19–50 months). In the period between cataract removal and secondary IOL implantation, all patients were prescribed contact lenses (overcorrected by +2D sphere initially, and reduced as clinically appropriate). Pharmacia Heparin Surface Modified AC IOL Model 722 C were implanted in 18 eyes, Acrysof MA60 BM IOL were implanted in 12 eyes and Hoya AF-1 IOL were implanted in six eyes. Mean follow-up after IOL implantation was 109.0± 33.8 months (range 42–228 months). During follow-up, reoperation was necessary in one case due to visual axis opacification 6 months after cataract removal. At last visit, the mean age was 7.35±2.9 years (range 4.3–15.0 years), and the refractive error was −2.28±2.5D (range, −7.50 to +2.50D). Myopic shift had occurred in four eyes (11.1 %; two patients, aged 5 months at the time of first intervention, 30 and 36 months at secondary IOL implantation). Mean BCVA at last visit was 0.54±0.4 ETDRS LogMAR. Six eyes (16.6%)

Table 2 Ocular alignment after bilateral congenital cataract surgery and primary or secondary intraocular lens (IOL) implantation

	Primary IOL implantation	Secondary IOL implantation	*P*
N	15	18	
Strabismus	6 (40 %)	12 (66.6 %)	0.07
Esotropia	2 (13.3 %)	8 (44.4 %)	0.1
Exotropia	4 (26.6 %)	4 (22.2 %)	0.8
DVD	2 (13.3 %)	3 (16.6 %)	0.2
Nystagmus	3 (20 %)	6 (33.3 %)	0.5

DVD, dissociated vertical deviation; *p* statistical significance between the two groups

presented a BCVA less than 20/200, while BCVA was between 20/200 and 20/40 in 18 eyes (50 %), and 20/40 or greater in 12 eyes (33.3 %). Nystagmus was present in six patients (33.3 %). Strabismus developed during follow-up in 12 cases (66.6 %; esotropia in eight cases, exotropia in four cases) and was operated in two cases, after 62 and 38 months. No cases of ocular hypertension were observed.

No significant differences were present between the two groups with regard to the type of cataract, mean axial length at the time of lens removal, type and power of the implanted IOL, BCVA at last visit, incidence of strabismus, and nystagmus during follow-up ($p>0.05$). A significantly greater incidence of myopic shift was observed in patients undergoing primary IOL implantation ($p<0.001$). No significant association was found in either group between age at cataract removal and final visual acuity, or between age at cataract removal and myopic shift ($p>0.05$). In each group, no significant differences of visual outcome were present among patients between 2 and 6 months, and older than 6 months at first surgery ($p>0.05$).

Discussion

To our knowledge, this is the first reported long-term comparison of primary versus secondary IOL implantation after simultaneous early removal of bilateral congenital cataract. Simultaneous surgery has been suggested to be preferable to deferred surgery, because it both reduces anesthesiologic risk in high-risk patients and decreases the risk of deprivation amblyopia [16–18]. Most studies have focused on the safety of this procedure [16, 19, 20]. Furthermore, a 21.9 % reduction in costs has been showed in association with bilateral simultaneous cataract surgery [21].

In our series, no significant differences of visual outcome were found between eyes that underwent primary IOL implantation and eyes that underwent secondary postponed IOL implantation. Posterior chamber IOL implantation after monolateral and bilateral congenital cataract removal has been shown to provide good visual outcomes and reduced postoperative complications [14, 22–34]. It has been suggested that visual outcomes are better in eyes treated with primary IOL implantation, because IOLs have the advantage of providing a full-time correction and a stable retinal image with minimal aniseikonia [35]. Better outcomes with earlier surgery were suggested by Birch et al. for removal of bilateral dense congenital cataracts [36]. Our results suggest the importance for visual outcome of an early cataract removal, notwithstanding whether IOL is implanted at the same time or after a period of contact lens use.

In our study, visual axis opacification was observed in only one case in the interval between cataract removal and secondary IOL implantation. Major factors affecting outcome after congenital cataract surgery are PCO obscuring the visual axis [37] and refractive error [28, 38]. The rate of PCO membranes in the literature is 45 % to 100 % when the posterior capsule is left intact [39–42], while the recurrence rate of secondary PCO membrane development decreases when a primary posterior capsulotomy and anterior vitrectomy at the time of IOL insertion are performed, as was the case in our series [43–47]. We observed no significant differences between the two groups concerning visual outcome and complications after the use of foldable hydrophobic (Acrysof MA60 BM and Hoya AF-1) or rigid polymethyl methacrylate IOLs (Pharmacia Model 722 C), as also suggested by other authors [48]. The use of newer generation IOLs, such as acrylic models, has also helped decrease the PCO membrane rate [40, 43].

Nystagmus was present before cataract surgery in 26.6 % of patients who underwent primary IOL implantation and in 38.8 % of patients who underwent secondary IOL implantation. Of them, 25 % and 14.3 % respectively improved after surgery. Preoperative strabismus or nystagmus is due to severe visual deprivation. Lu et al. showed that preoperative nystagmus favourites a poor visual prognosis [49], while Yagasaki et al. suggested that the nystagmus frequently resolves when bilateral congenital cataract surgery is performed within a month of the onset of the nystagmus [50]. In our series, cataract removal later than 1 month of life did not allow effective improvement of preoperative nystagmus.

Myopic shift was more frequent in the group undergone primary IOL implantation (26.6 % vs 11.1 %, $p<0.001$), suggesting that the presence of an IOL in early months of life may affect subsequent eye growth. Our data agree with the previously reported greater axial elongation in pseudophakic eyes [51–55].

In our series, both primary and secondary IOL implantation after early cataract removal with posterior capsulotomy and central anterior vitrectomy provided a low incidence of glaucoma (one out of 66 eyes) during long-term follow-up. Several studies report that cataract extraction with primary IOL implantation is safe in selected older children, and chronic glaucoma in these eyes is uncommon [55–59]. Development of glaucoma has been suggested to be more common if surgery is performed very early [60, 61]. Trivedi et al. [57] reported an incidence of glaucoma of 3.8 % in pseudophakic eyes and 17 % in aphakic eyes. As suggested by Asrani et al. [62], the reduced incidence of glaucoma in pseudophakic eyes could be due to the blockage by the IOL and posterior capsule of a vitreous chemical component toxic for the trabecular meshwork, and to the support exerted by the IOL to the trabecular meshwork, which would prevent disorganization and damage that lead to glaucoma over the long term. Central anterior vitrectomy could further limit the toxic effects of the vitreous on the trabecular meshwork. Low incidence of glaucoma may also

be due to the refined surgical technique and 'in-the-bag' IOL implantation.

Limitations of this study are the retrospective design and the relatively small sample size in the two groups, mainly because of the relatively low number of simultaneous bilateral congenital cataract surgery performed at the beginning of the study period. On the other hand, major strengths are the length of follow-up and the reduced bias in surgical technique due to the presence of a sole operator.

In conclusion, our results suggest that after simultaneous removal of non-complicated bilateral congenital cataract with posterior capsulotomy and central anterior vitrectomy, both primary or secondary IOL implantation may provide similar long-term functional outcome and incidence of complications, except for a higher incidence of myopic shift when IOL is inserted during first 12 months of life. A prospective study is needed to confirm these data.

Conflict of interest The authors do not have any financial conflict of interest in the subject matter in the manuscript.

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