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CATARACT

Visual results and complications of primary intraocular lens implantation in infants aged 6 to 12 months

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Abstract
Background To present the visual results and the complications of primary intraocular lens (IOL) implantation in infants aged 6 to 12 months between January 2002 and July 2007.
Methods A total of 26 consecutive eyes, of 16 infants with cataract aged 6 to 12 months, were reviewed in the study. All patients had cataract extraction with anterior and posterior capsulorrhexis combined with anterior vitrectomy and primary hydrophobic acrylic IOL implantation. Six infants (six eyes) had unilateral congenital cataract and ten (20 eyes), bilateral cataract. Visual acuity and complications were recorded throughout the 46.4-month mean follow-up (range 22 to 79 months).
Results All eyes had primary IOL implantation. The mean best-corrected visual acuity (logMAR) was 0.98±0.18,0.50± 0.14 and 0.61± 0.25 for unilateral, bilateral and all eyes respectively at the last follow-up. IOLs were implanted in the capsular bag of 25 eyes (96.2%) and in the sulcus of the remaining one eye (3.8%). Seven eyes (26.9%) developed visual axis opacification (VAO), and four eyes required secondary pars plana vitrectomy (PPV). IOL opacification occurred in one eye 54 months after implantation. Late onset open-angle glaucoma developed in one eye, and required trabeculectomy surgery. The predictors of good best-corrected visual acuity (BCVA) included partial cataract, bilateral cataract, absence of strabismus or nystagmus, and good amblyopic treatment. The greatest annual myopic change (5.15±2.08 D) was observed during the first 12 months after surgery. In unilateral cases, there was no significant difference in the axial length between the cataractous eye and the fellow normal eye both at the time of surgery (P=0.891) and final follow-up (P=0.693).
Conclusions Primary IOL implantation was safe and effective for infantile cataract surgery. Total or unilateral cataract, nystagmus or strabismus, and inadequate amblyopic therapy were predictors of poor BCVA. Significant myopic shifts occurred especially in infants in the first year of surgery. The pseudophakic eye had a similar growth rate, as measured by axial length, to that of the fellow normal eye, in unilateral cases.

Keywords Infantile cataract extraction · Intraocular lens · Congenital disorder · Primary posterior capsulorrhexis · Visual acuity

Yi Lu and Ying-Hong Ji contributed equally to this work.

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The authors have full control of all primary data, and agree to allow Graefe's Archive for Clinical and Experimental Ophthalmology to review the data upon request.

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Introduction

In recent years, an increasing number of ophthalmologists have accepted IOL implantation as a mode of aphakic rehabilitation in children of 2 years old and, in some cases, younger [1]. Although primary IOL implantation in infants is not the standard of management, some surgeons have reported complications and visual results of primary intraocular lens implantation in children younger than 1 year

old [2–5]. It has been reported that a younger age at the time of surgery, has been positively correlated with the development of postoperative complications requiring secondary surgery. The incidence of re-operations is highest in infants during the first 6 months of age [6, 7]. Plager and collegues [7] reported that 80% of infants aged 6 months or below receiving primary capsulotomy and vitrectomy had secondary visual axis opacification requiring a repeat pars plana vitrectomy (PPV). For cataract infants, age is a crucial factor in the prognosis of surgery; the younger the infants are, the more complications can occur. Few reports about complications and visual results have been recorded in the literature, especially in cataract infants aged 6 to 12 months. Here, we review our experiences with regard to infants aged 6 to 12 months with primary hydrophobic acrylic IOL implantation.

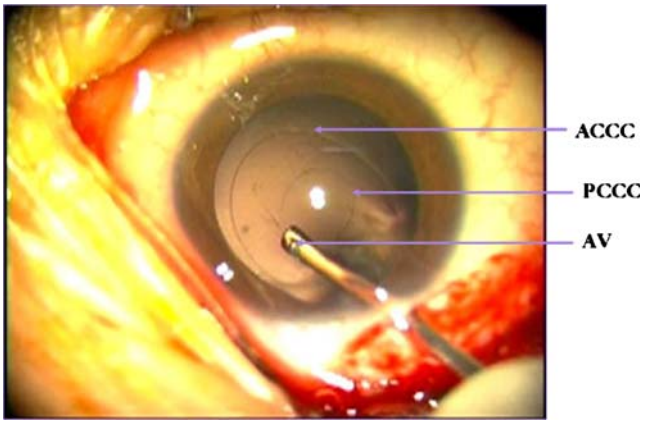

Fig. 1 Intraoperative photograph showing the procedure of ACCC, PCCC and AV. *ACCC* = anterior continuous curvilinear capsulorrhexis; *PCCC* = posterior continuous curvilinear capsulorrhexis; *AV* = anterior vitrectomy

Patients and methods

A retrospective analysis of 26 eyes of 16 infants aged 6 to 12 months who had cataract extraction and IOL implantation between January 2002 and July 2007, was carried out. All patients had the operation performed by the same surgeon (Y. Lu) at the Eye & ENT Hospital of Fudan University, Shanghai, China. Infants with associated ocular defects such as retinopathy of prematurity, persistent fetal vasculature, uveitis, congenital glaucoma, microphthalmos, or other anterior and posterior segment anomalies were excluded from the study. Considering the safety of cataract surgery, infants less than 6 months underwent cataract extraction without IOL implantation, and these cases were excluded from this study. All parents signed the informed consent form, which was approved by the local ethical committee.

Prior to surgery, axial length was measured by an ultrasonic A-scan (Nidek US-800, Japan). Lens power calculations with SRK-T formula were based on an average corneal power of 48.00 to 46.00 diopter (D) in the 6- to 12-month age group. 30% was deducted from the emmetropic IOL power; the reduced value was about +6.00 to +8.00 D.

All surgeries were performed under general anesthesia. After the superior scleral tunnel was created, a 5- to 6-mm diameter anterior continuous curvilinear capsulorrhexis (ACCC) was performed, then the cortex and soft nucleus were aspirated utilizing automatic I/A with an I/A handpiece. In the presence of calcified cataracts, a phacoemulsification handpiece was used. A small tear was made at the center of the posterior capsule using a syringe needle, viscoelastic agent was injected through the tear to separate the posterior capsule from the anterior limiting membrane of the vitreous, then a 3- to 4-mm diameter posterior continuous curvilinear capsulorrhexis (PCCC) was made with capsulorrhexis forceps; then an anterior vitrectomy (AV) was performed, through the scleral tunnel incision, to remove the anterior central vitreous without irrigation (Fig. 1). Hydrophobic acrylic foldable IOLs were implanted, using the injector. The tunnel incision was closed with one 10-0 nylon suture. At the end of surgery, subconjunctival gentamycin and dexamethasone were injected, and Tobradex ointment was applied.

Postoperatively, all patients received topical eyedrops of steroid and non-steroid anti-inflammatory drugs (NSAIDs). The immediate postoperative refraction was performed 2 weeks after surgery, and the residual refractive error, with an additional +2.50D of correction to provide near-point correction, was prescribed on spectacles. In most cases, occlusion therapy for the fellow eye was prescribed every other day in unilateral cases. Amblyopic compliance was categorized as good if 75% to 90% of prescribed hours were reported, and as poor if 0% to 50% were reported.

The patients were examined postoperatively at 1 day, 1 week, 2 weeks, 1 month, and at intervals of 6 months. IOP was measured with a Tono-pen™ tonometer or a pneumotonometer. Final best-corrected visual acuity was recorded on a Snellen scale of 20/200 to 20/20 in cooperative patients.

The refractive error was calculated as the spherical equivalent (SE) refraction using the algebraic power of the sphere plus half the cylindrical power. Visual acuities were converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis. Statistical analysis in this study included Fisher exact test and independent sample *t*-test. All tests were two-tailed, and acceptable significance was recorded when *P* values were less than 0.05. Statistical analyses were performed using the SPSS program for Windows (SPSS Institute, Chicago, IL, USA).

Table 1 Demographics of infants having cataract surgery and IOl implantation

Patient/eye	Cataract types	Age at surgry (months)	Follow-up(months)	Reoperations	BCVA
Unilateral cataract					
1	Nuclear	7	22	None	Failure*
2	Nuclear	8	35	None	20/200
3	Posterior polar	6	46	None	20/125
4	Nuclear	9	54	PPV×1	20/400
5	Posterior polar	8	58	None	20/200
6	Posterior polar	10	79	None	20/125
Bilateral cataract					
7R	Total	6	26	None	20/100
7L	Total	6	26	None	20/100
8R	Nuclear	10	38	None	20/63
8L	Nuclear	9	39	None	20/50
9R	Nuclear	9	59	PPV×2	20/100
9L	Nuclear	8	60	None	20/80
10R	Total	6	35	None	20/80
10L	Total	7	34	None	20/80
11R	Posterior polar	7	46	PPV×1	20/63
11L	Posterior polar	7	46	None	20/50
12R	Lamellar	8	64	None	20/50
12L	Lamellar	9	63	None	20/50
13R	Nuclear	11	72	Glaucoma surg×1	20/40
13L	Nuclear	10	73	None	20/40
14R	Membrane	8	31	PPV×1	Failure*
14L	Membrane	10	29	None	Failure*
15R	Nuclear	10	48	None	20/63
15L	Nuclear	12	46	None	20/63
16R	Total	9	39	None	20/80
16L	Total	10	38	None	20/80

BCVA = best-corrected visual acuity, PPV = pars plana vitrectomy, *means that child didn't cooperate to permit measurement of BCVA

Results

Twenty-six eyes of 16 infants were included in the study. All the infants had congenital or developmental cataracts. Six infants (six eyes) had unilateral congenital cataract, and ten infants (20 eyes) had bilateral cataract (Table 1). Six infants (12 eyes) had nystagmus, and four infants (four eyes) had strabismus before surgery. The mean age at surgery was 8.5 months (range 6 to 12 months). The mean follow-up was 46.4 months (range 22 to 79 months).

All eyes had primary IOL implantation. One-piece hydrophobic acrylic IOLs (AcrySof™ SA series, Alcon) were implanted in the capsular bag of 25 eyes (96.2%), and a three-piece IOL (AcrySof™ MA series, Alcon), was implanted in the remaining eye (3.8%), and was sulcus-fixated due to a large rupture of the posterior capsule.

Seven eyes (26.9%) developed visual axis opacification of (VAO), and four eyes required secondary pars plana

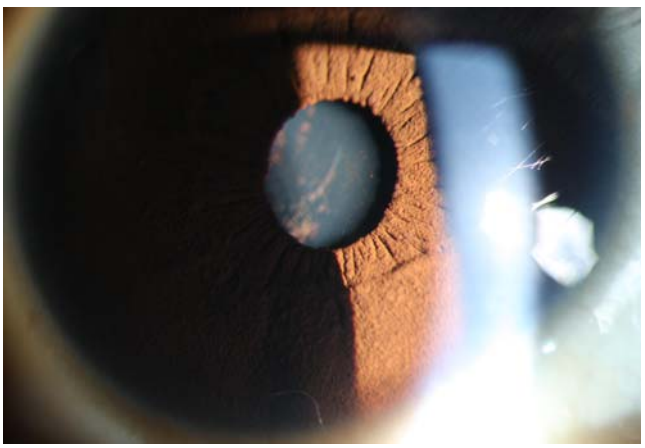

Fig. 2 Opacification of hydrophobic acrylic IOL in one eye

vitrectomy (PPV) after a mean 9.8 months (range 5 to 15 months) from surgery. One eye needed PPVs twice.

Eighteen eyes (69.2%) retained a clear visual axis during the follow-up period. One eye developed IOL optic opacification 54 months after implantation (Fig. 2), with a best-corrected acuity of 20/80. Pupil capture was observed in two eyes (7.7%). Late-onset open-angle glaucoma was found in one eye at the 48th month follow-up. Trabeculectomy surgery was performed in this case.

In all eyes, the median best-corrected visual acuity was 20/80 (range 20/400 to 20/50) (Table 1); the mean best-corrected visual acuity (logMAR) was 0.98±0.18,0.50±0.14 and 0.61±0.25 for unilateral, bilateral and all eyes respectively. The predictors of good BCVA included partial cataract, bilateral cataract, absence of strabismus or nystagmus, and good amblyopic compliance with treatment (Table 2). Six infants (12 eyes) had nystagmus before surgery, which disappeared in three cases (six eyes) during the follow-up period.

The axial lengths of the 26 eyes ranged from 18.16 to 21.27 mm (mean 19.34±1.15 mm) at the time of operation with the IOL power range from 18.0 to 30.0 D (mean 22.46±2.14 D). The mean refraction immediately after 2 weeks of surgery was +5.42±2.41 D. The myopic shift from the refraction immediately after surgery to the final refraction was observed at 12, 24, 36, 48, 60 and 72 months after surgery. The mean value of myopic progression were 5.15±2.08D, 6.46D±2.13D, 7.54±3.16D, 7.92D±3.40D, 8.25±3.57 and 8.67±3.62D; the number of eyes observed at each of these post-operative visits were 23, 22, 18, ten, six and three respectively. The greatest annual myopic change was observed in the first 12 months after surgery.

For the six unilateral cases, there was no significant difference in the axial length at the time of operation between the cataractous eye (mean 19.80±0.41 mm) and the fellow normal eye (mean 19.77±0.42 mm) (P=0.891). Interestingly, there was no significant difference in the final axial length of the pseudophakic eye (mean 22.61±1.16 mm) compared to the fellow normal eye (mean 22.38±0.80 mm) (P=0.693).

Discussion

Recently, IOLs are rapidly replacing contact lenses for the correction of aphakia in infants [1], Other results showed an improved visual outcome for unilateral congenital cataract, but a higher rate of complications requiring reoperation [6, 8, 9]. Part of the success of successfully correcting aphakia with IOL in infants may be due to the development of foldable IOLs, which are now being increasingly used in pediatric eyes, especially the AcrySof™ IOL [10]. We chose this single-piece foldable acrylic IOL (SA Series) from the Alcon company because the lens has very flexible haptics that facilitate 'in the bag' implantation in infants and minimizes ovaling of the capsulorrhexis' opening with a lower incidence of PCO [11–13], and we chose 3-piece Acrysof™ MA series IOL 'in the sulcus' in the case with a large rupture of the posterior capsule [14].

Visual axis opacification (VAO) is the first complication of concern to us, which is due to the fibrous membranes, associated with lens epithelial cell proliferation, on the posterior surface of IOL. In our series, we found VAO in 26.9% of all eyes, although we managed it with posterior capsulorrhexis and anterior vitrectomy. Lundvall et al. reported that 70% of infants aged 8 days to 10 months developed secondary opacification requiring additional surgery, even though a posterior capsulorrhexis and anterior vitrectomy were performed [2]. Trivedi et al. [15] also demonstrated that a secondary surgical procedure was required in 37.9% of eyes to maintain a clear visual axis within the first year of life. The incidence of VAO in our study is lower than those studies, because the infants in our study were beyond 6 months of age; the younger the infants are, the higher the incidence of VAO are [16]. However, we don't know if the surgical procedure we performed had an effect on our incidence.

The hydrophobic acrylic IOL is widely used in children throughout the world nowadays [10]. However, in this study we found opacification of one Acrysof™ IOL was detected 54 months after implantation. We anticipate performing a 'lens exchange' on this child in the future. Since opacification of IOL optics has been described with

Table 2 Association of pre or postoperative factors and BCVA after primary IOL implantation

	No. of eyes	Type of cataract		Unilateral or binocular		Strabismus or nystagmus		Amblyopia therapy	
		Total	Partial	Unilateral	Bilateral	Yes	No	Poor	Good
BCVA >20/80	10	0	10	0	10	2	8	1	9
BCVA ≤20/80	13	6	7	5	8	11	2	9	4
P		0.019*		0.046*		0.003*		0.010*	

BCVA = best-corrected visual acuity, *significant, P<0.05, Fisher's exact test

all types of IOL material including poly(methylmethacrylate), hydrophilic acrylic, silicone and hydrophobic acrylic. We look forward to a kind of material that is safer, especially for infants. The 'glistening' of Acrysof™ IOL have previously been reported [17, 18]. Differently, the clinical appearance of the Alcon Acrysof™ IOL, in our study, was that of a clouding in the lens optic similar to hydrophilic acrylic IOL from Medical Developmental Research [19, 20].

IOL power calculation remains a big problem in infantile cataract surgery, because an infant with pseudophakia is expected to experience a large myopic shift as the eye develops. McClatchey and Parks [21] calculated the theoretical long-term refractive effects of pseudophakia in a large group of pediatric aphakic eyes with long-term follow-up, and predicted a 6.6 diopter mean myopic shift over a mean follow-up of 11 years. With 3-year follow-up, Fan DS et al. [3] reported a mean myopic progression of 7.11 D in the pseudophakic eyes of 20 children who underwent IOL implantation during the first year of life. Enyedi et al. [22] recommended a postoperative refractive goal of +6 for a 1-year-old, +5 for a 2-year-old, +4 for a 3-year-old. In the present study, the myopic shift in infants was 5.15 D, 6.46D, 7.54D, 7.92D after 12, 24, 36 and 48 months respectively. The major myopic progression occurred more rapidly during the first 12 months, although there was still myopic shift even in the sixth year. Based on our methods of IOL calculation, the value of myopic shift is approximately similar to the deducted IOL value of 6D to 8D. It's suggested that our anticipation of emmetropia over time was relatively accurate.

As for the corneal curvature, rapid flattening of the corneal curvature occurs during the first year of life, especially the first 6 months, and 90% of the eye's growth occurs in the first 2 years [23]. Asbell and colleagues [24] noted their mean corneal curvature of newborn to 6 month-old to be 47.59 D. The value decreases to 46.30 D in the 6- to 12-month age group, drops further to 45.56 D in the 12- to 18-month-old group, and stabilizes at about 54 months with an average reading of 42.69 D. In view of this, we chose the average corneal power of 48.00 D to 46.00D for 6- to 12-month infants as theoretical keratometry readings, because infants can't be examined by an adult autokeratometer. Recently, handheld keratometry has become available, and this offers the convenience of obtaining K measurements in children under anesthesia. This is an accurate and convenient method of obtaining the actual K value.

Ledoux DM et al [25] reported that the mean visual acuity of infantile pseudophakic children surgery at an age less than 1 year was 20/258 and 20/60, while the mean visual acuity of all pediatric eyes from birth to 18 years was 20/80 and 20/34 in unilateral and bilateral groups; usually the infants had poorer visual acuity outcome than the older categories [25]. Our results showed that the mean best-corrected visual acuity (logMAR) was 0.98 (20/191) and 0.50 (20/63) for unilateral and bilateral groups, which are similar to the above study. Bilateral cataracts had better visual outcome than that of unilateral cataracts; this is maybe because bilateral pseudophakia accepts amblyopic treatment more easily. Despite a satisfactory anatomical outcome of primary IOL implantation, functional outcome remains relatively poor. To prevent irreversible amblyopia, it is suggested that cataract surgery is performed before the age of 6 weeks [26]. However, one must bear in mind the higher rate of IOL complications and the uncertainties of IOL power calculation in the younger age group, together with technical difficulty of surgery [27]. Either contact lens or IOLs can be used for the correction of aphakia. A randomized multicenter clinical trial (Infant Aphakia Treatment Study, IATS) supported by the National Eye Institute is planned to compare IOL and contact lens correction for unilateral aphakia for infants aged 28 to 210 days.

Preoperative strabismus or nystagmus is due to severe visual deprivation, and post-operatively most of these eyes had poorer vision. However, interestingly several preoperative nystagmus cases in our series did resolve postoperatively. If cataract surgery is performed within a month of the onset of the nystagmus, the nystagmus will frequently resolve [28]. The strabismic angle was reduced postoperatively in some infants, supporting the observation that visual function may benefit from pseudophakic surgery.

It is well-known that amblyopic treatment is important so that the pseudophakic eyes can develop the optimum visual acuity, and that the final visual acuity is correlated to compliance with amblyopic treatment. The immediate postoperative refraction in our series was +5.42 D; the residual refractive error should be corrected by spectacles or contact lenses. Typically, occlusion therapy is essential, especially in eyes with unilateral cataract. Only 13 out of the 26 eyes in our study had good compliance with amblyopic treatment. The compliance rate was lower than the previous study [29]; this may be due to the longer travelling distance, poor understanding of the importance of amblyopic therapy and or family socio-economic factors.

Axial growth after cataract surgery can be attributed to normal eye growth as well as other factors, including age at surgery, visual input, the presence or absence of an IOL, laterality, genetic factors, and axial length differences [30, 31]. In our study, we found no difference in preoperative and postoperative axial length measurements between the cataractous and the normal fellow eyes among the unilateral pediatric cataract children.

In conclusion, 'partial cataract', bilateral cataract, absence of strabismus or nystagmus, and good amblyopic

treatment were significant for good BCVA. Significant myopic shifts especially occurred in infants and were most marked in the first year following surgery. In unilateral cataract cases, the pseudophakic eye had a similar growth rate, as measured by axial length, to the fellow normal eye.

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