Primary and Secondary Intraocular Lens Implantation in Congenital Cataract Surgery: A Retrospective Comparative Study of the Visual Outcomes

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Abstract

Objectives: To compare visual outcomes, principally myopic shift, visual acuity, intraocular pressure and strabismus between primary and secondary intraocular lens (IOL) implantation following congenital cataract surgery.

Methods: A retrospective study of the long-term ocular outcomes in primary versus secondary IOL implantation (IOL-I) following congenital cataract surgery was conducted. We analyzed the files of all children with congenital cataract who underwent unilateral or bilateral lensectomy, posterior capsulotomy and anterior vitrectomy followed by primary or secondary IOL-I between 2000 to 2012, at King Abdulaziz University Hospital, Jeddah. Preoperative and postoperative assessment of each operated eye in terms of axial length, refractive errors, strabismus as well as (post IOL-I) intraocular pressure (IOP) and best corrected visual acuity (BC-VA) were collected and analyzed.

Results: Data of 26 eyes of 14 patients (9 males, 6 females) was analyzed: 16 (61.5%) eyes underwent lensectomty and anterior vasectomy with primary IOL-I and 10 (38.5%) eyes underwent lumpectomy and anterior vasectomy with secondary IOL-I. Mean age at cataract surgery was 67.53 (\pm 48.70) months in the group of primary IOL-I versus 5.90 (\pm 3.72) months in the group of secondary IOL-I; and patients were followed up for 49.33 (\pm 26.23) versus 86.50 (\pm 23.36) months, respectively (p=.051). In the secondary IOL-I group, the mean of time from primary lensectomy to IOL-I was 50.44 (\pm 18.41) months.

Last BC-VA showed better outcomes in primary IOL-I group as 10 eyes (83.3%) with good VA versus only 2 eyes (20%) in the secondary IOL-I, (p=0.009). Myopic shift was greater in secondary IOL group 10.86 (\pm 11.62) versus 0.19 (\pm 2.38) diopters (D) in primary IOL (p=0.046*); while no significant difference was observed in IOP (p=0.697). No case of isotropic was detected in primary versus 6 cases in the secondary IOL group.

Conclusion: Visual outcomes, including visual acuity, strabismus and myopic shift were better in the group of children who underwent primary IOL implantation at age of >2 years, when compared to those with secondary IOL implantation at the age of <2 years, following congenital cataract surgery. However, poor visual acuity in the secondary IOL group was mainly explained by the relatively higher prevalence of eye complications in this group.

Introduction

Congenital cataract is the third common cause of visual impairment in children in Saudi Arabia, after hereditary retinal disorders and congenital glaucoma [1]. The common factors associated with its incremental development include a various prenatal metabolic, toxic, infectious or genetic conditions [2,3]. The consensual treatment of congenital cataract consists of early surgical removal of the cataractous lens to prevent vision impairment and irreversible amblyopia [4,5]. On the other hand, aphakia, is a frequent complication following cataract extraction [6]. That may

lead to other eye complications, such as glaucoma, if not treated with timely intraocular lens implantation (IOL-I) [7,8]. Therefore, IOL-I is best treatment for congenital cataract.

In children <2 years of age, primary IOL implantation is not reputed to be the best option, due incomplete physiological growth of the eyes at that age. The myopic shift resulting from the growthrelated biometric changes of the eye during the early years of life, including changes in the power of the cornea and rapid increase in the axial length of the globe, leads to ultimate inadequacy of power of the implanted lens [2-4]. The best alternative in this age group is the secondary IOL-I. It is often performed after few years following cataract extraction with generally good visual outcomes, with the optional use of contact lenses before the IOL implant [8,9]. However, some authors support the early IOL-I in this age group (<2 years). They believe that there are some advantageous visual outcomes and that the associated visual adverse events are outweighed by those subsequent to infantile aphasia [10]. As a consequence, other controversies are raised regarding the correct IOL to be used and appropriate biometry measurements; not only for this age category, but for all the pediatric population [9].

The present study compares the long-term visual outcomes, principally myopic shift, visual acuity, intraocular pressure (IOP) and strabismus between the two populations of children with congenital cataract who underwent primary and those who underwent secondary IOL-I.

Methods

This was a retrospective study of the long-term ocular outcomes in primary versus secondary IOL-I following congenital cataract surgery. We analyzed the files of all children with congenital cataract who underwent unilateral or bilateral lumpectomy, posterior capsulotomy and anterior vasectomy followed by primary or secondary IOL-I between 2000 and 2012, at King Abdul-Aziz University Hospital (KAUH), Jeddah, Saudi Arabia. Preoperative and postoperative assessment results of each operated eye in terms of axial length, refractive errors, ocular alignment, as well as postoperative (post IOL-I) IOP and visual acuity were collected and analyzed. The study was conducted in agreement with the terms of the declaration of Helsinki and approved by the institutional review board of KAUH

Surgical method

All surgeries were performed by an experienced eye surgeon under general anesthesia, irrigation and aspiration of the lens. Posterior capsulotomy and anterior vasectomy were done in both groups. According to routine practice in our department, the minimum age for primary IOL-I was 2 years [2-4]. Thus, for any patient aged \geq 2 years, an IOL was implanted immediately after vasectomy (primary IOL-I group), either in the ciliary sulcus or in between anterior and posterior capsules. For patients <2 years, the IOL was implanted later on (secondary IOL-I group) in the ciliary sulcus. The type of the IOL used was a foldable Acrysof multipice (Alcon Laboratories, INC, Texas USA). The power of IOL ranged between 16.00 and 25.50 (mean \pm SD = 21.57 \pm 3.16) diopter for

primary IOL group and between 16.50 and 24.00 (mean \pm SD = 21.23 \pm 2.65), diopter for secondary IOL group, (p=0.793). No intraoperative complications were reported in both the groups. Topical antibiotic was administered and the eye was patched with a cover shield. The eye was treated with topical antibiotic, steroid and cyclopentolate eye drops, postoperatively.

Assessments

Demographic and clinical data was collected. Intraocular lens power was determined on the basis of axial length and keratotomy readings, by using Sanders-Retzlaff-kraff II formula. Preoperative and postoperative axial length was measured by biometry, using A-SCAN Bio meter palm Scan A2000T (Micro Medical Devices, California USA). Postoperative refractive errors, visual acuity, intraocular pressure and strabismus were assessed using auto refraction, snellen chart, air puff and krimsky test/cover test or hirshisburg test, respectively. The degree of deviation was measured in prism diopters.

Statistical Methods

Statistical analysis was performed using Statistical Package for Social Sciences version 16.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics was used to determine frequencies and percentages of categorical variables and mean standard deviations (SD) of continuous variables. Change in axial length (mm) was computed by subtracting the preoperative measurement from the postoperative measurement and was analyzed as a continuous variable. Comparative analysis between primary and secondary IOL-I was carried out using chi-squared test for categorical data and independent t-test for continuous data. The significance level was set for a P < 0.05.

Results Baseline

Data of 26 eyes of 14 patients (9 males, 6 females) was analyzed. These included 16 (61.5%) eyes that underwent lensectomy, anterior vasectomy with primary IOL-I versus 10 (38.5%) that underwent lensectomy, anterior vasectomy with secondary IOL-I; with follow-up periods of 49.33 (\pm 26.23) and 86.50 (\pm 23.36) months, respectively (p=.051). Mean age at cataract surgery was 67.53 (\pm 48.70) months in the group of primary IOL-I versus 5.90 (\pm 3.72) in the group of secondary IOL-I, (p=0.001). Comparison of mean preoperative axial length of the eyes showed no significant difference between the two groups (22.35 [\pm 0.96] mm versus 21.85 [\pm 0.56] mm, p=0.173). In the secondary IOL-I group, the mean time duration from primary lensectomy to secondary IOL-I was 50.44 (\pm 18.41) months (Table 1).

Outcomes

Axial length: Preoperative assessments of axial length showed no significant difference between the two eye groups: with mean axial length = $22.29 \text{ mm} (\pm 0.69)$ versus $21.27 \text{ mm} (\pm 2.55)$ in the group of primary IOL-I versus that of secondary IOL-I, respectively, (p=0.378). Similarly, the mean change in axial length from preto postoperative assessments showed no significant difference between the two groups, $-0.57 (\pm 0.56)$ versus $-0.28 (\pm 2.33)$,

(p=0.756). In addition, paired anal-ysis showed no difference between pre and postoperative axial length in the total study population (p=0.313) (Table 2).

Parameter		Primary IOL implantation	Secondary IOL implantation	p-value
Number eyes (%)/ patients		16 (61.5%)/9	10 (38.5%) /5	-
Male/ Female		5/4	4/1	-
Age at cataract surgery, mean (SD), months		67.53 (48.70)	5.90 (3.72)	5.90 (3.72)
Side, N (%)	Right eye	9 (56.2%)	5 (50.0%)	1.000
	Left eye	7 (43.8%)	5 (50.0%)	
Preoperative axial length, mean (SD), mm		22.35 (0.96)	21.85 (0.56)	.173
Time to secondary IOL implantation (months)		-	Mean (SD) = 50.44 (18.41), range = (24, 84)	
Age at last visit, mean (SD), years		11.4 (5.73)	7.00 (1.63)	.165
Duration of follow-up, mean (SD), months		49.33 (26.23)	86.50 (23.36)	.051

Table 1: Demographic and baseline data. IOL: intraocular lens; SD: standard deviation.

Parameter	Primary IOL implantation	Secondary IOL implantation	p-value
Number (eyes)	16 (61.5%)	10 (38.5%)	-
Strabismus			
Esotropia	0 (0.0%)	6 (60.0%)	.006*
Exotropia	1 (8.3%)	0 (0.0%)	
None	11 (91.7%)	4 (40.0%)	
Nystagmus	0 (0.0%)	4 (40.0%)	-
Axial length (mm)	22.29 (±0.69)	21.27 (±2.55)	.378
Change in axial length (mm)	-0.57 (±0.56)	-0.28 (±2.33)	.756
Myopic shift (diopters)	0.19 (±2.38)	-10.86 (±11.62)	.046*
Postoperative IOP: mean (SD); (mmHg)	14.5 (±3.98)	15.5 (±5.29)	.697
Visual acuity § (n=22)			
Good	10 (83.3%)	2 (20.0%)	
Fair	2 (16.7%)	5 (50.0%)	.009*
Poor	0 (0%)	3 (30.0%)	

Table 2: Postoperative ocular alignment and visual acuity in primary versus secondary IOL implantation. IOL: intraocular lens; SD: standard deviation; * Statistically significant results; \S visual acuity: good (from 20/20 to 20/50 or central steady maintained); fair (from 20/60 to 20/100 or central steady unmaintained); poor (> 20/100, no light perception, central unsteady unmaintained, or uncentral unsteady unmaintained).

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of primary IOL-I versus that of secondary IOL-I, respectively, (p=0.378). Similarly, the mean change in axial length from preto postoperative assessments showed no significant difference between the two groups, -0.57 (\pm 0.56) versus -0.28 (\pm 2.33), (p=0.756). In addition, paired anal-ysis showed no difference between pre and postoperative axial length in the total study population (p=0.313) (Table 2).

Visual acuity

Last best corrected visual acuity (BC-VA) assessments showed better outcomes in primary IOL-I group with 10 (83.3%) of the eyes with good VA (central steady maintained or snellen equivalent better than or equal to 20/50) and 2 (16.7%) with fair VA (snellen equivalent 20/60-20/100 or central steady unmaintained) and no case (0%) with poor VA (snellen visual acuity more than 20/100, central unsteady unmaintained or uncentral unsteady unmaintained). Whereas, in secondary IOL-I group only 2 (20.0%) eyes had a good VA (central steady maintained or snellen equivalent better than or equal to 20/50), 5 (50.0%) with fair VA (snellen equivalent 20/60-20/100 or central steady unmaintained) and 3 (30.0%) had a poor VA (snellen visual acuity more than 20/100, central unsteady unmaintained or uncentral unsteady unmaintained), (p=0.009) (Table 2).

Strabismus

Postoperative assessments of strabismus showed no cases of isotropic and one single case of exotropia after primary IOL-I, versus 6 (60.0%) cases of isotropic and no cases of exotropia after secondary IOL-I, (p=0.006) (Table 2).

Intraocular pressure

Analysis of mean intraocular pressure (IOP) showed non-statistically significant difference between primary (14.5 [\pm 3.98]) mmHG and secondary (15.5 [\pm 5.29]) mmHG IOL-I, (p=0.697) (Table 2).

Myopic shift

Analysis of mean myopic shift showed 0.19 (\pm 2.38) in primary IOL group and -10.86 (\pm 11.62) after secondary IOL group, (p=0.046) (Table 2).

Refractive errors

In early postoperative period (<1 year), the frequency of myopic refraction was 5 (31.2%) in primary group versus 1 (10.0 %) in secondary group and that of hypermetropic refraction was 6 (37.5%) in primary group versus 6 (60.0%) in secondary group, (p=0.316). The mean (SD) measurement of hypermetropia was significantly lower (+2.46 [\pm 0.90] diopter, n=6) in case of primary IOL-I than in that of secondary IOL-I (mean = +18.17 [\pm 3.12] diopter, n=6), (P<0.001).

In late (>1 year) postoperative assessments, the frequency of myopic refraction was $5\,(31.2\%)$ in primary group versus $3\,(30.0\%)$ in secondary group and that of hypermetropia was $2\,(12.5\%)$ in primary group versus $6\,(60.0\%)$ in secondary group, (p=0.316). The mean (SD) measurement of myopia was significantly lower

(-1.75 [\pm 1.07] diopter, n=5) in case of primary IOL-I than in that of secondary IOL-I (-8.17 [\pm 3.87] diopter, n=3), (P<0.011). Similarly, the mean (SD) measurement of hypermetropia was significantly lower (+2.25 [\pm 1.06] diopter, n=2) in case of primary IOL-I than in that of secondary IOL-I (+11.33 [\pm 7.53] diopter, n=6), (P<0.031).

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Discussion

The results of this retrospective study showed superior visual outcomes in the group of children who benefited from primary IOL-I, in comparison with those who benefited from secondary IOL-I. These outcomes consisted of better results in visual acuity assessment and significant reduction in the prevalence of strabismus and in the extent of myopic shift.

However, the design of this study does not provide evidences of superiority of primary IOL-I in any age group. Age was a major confounder, as the two groups were divided by the indication (primary versus secondary IOL-I), which basically depended on age distribution. In addition, the collected data was not sufficient to carry out further age-adjusted sub-group analysis.

Many authors have recommended different age limits as an

indication for primary IOL-I. It was demonstrated that axial length increases by 8 mm from birth to adulthood [2]. Some authors argued that primary IOL in very young children presents a risk for suture leakage and increases the risk of aphakic glaucoma, which develops in the few years following the intervention [6-9]. According to the studies from the USA and another from Mexico, which retrospectively studied populations of patients aged in average between 5 and 7 at time of the surgery, better visual outcomes were achieved in older population after primary IOL-I, as compared with younger patients [11,12]. In addition to age factor, both teams agreed that bilateral surgeries are associated with better results than unilateral cases. Except a few authors, it is largely advocated that primary IOL-I is the standard option for children aged ≥ 2 years. In his study, Struck suggested that primary IOL-I should be indicated in children aged ≥7 months at the time of cataract surgery, supporting that favorable visual outcomes were comparable to those in children in older age groups [10]. Other authors remained skeptical about implanting an IOL in children aged <2 years, emphasizing the significant risks of myopic shift, uveitis and posterior capsular opacifications and the related visual outcomes [4].

Assessments of visual outcomes showed 30% cases of poor and 50% of fair visual acuity in secondary IOL-I group. Whereas, in primary IOL-I group, 83.3% of cases had good visual acuity and no case of poor visual acuity was observed. The interpretation of these results should be done with caution, as the poor visual acuity found in secondary IOL-I group was multifactorial. Two out of the five patients from secondary IOL-I group had Down syndrome, which featured refractive errors that further contributed to the low visual acuity in this group. A few other complications were observed in this group, including 2 cases of nystagmus, 1 case of corneal edema and 1 case of posterior capsule pacification. Thus, the poor visual outcomes in this group cannot be attributed to secondary IOL-I, which does not support the superiority of primary IOL in visual acuity. However, if we incorporate visual acuity and complications, the superiority of primary over secondary IOL-I could be admitted in a safety and efficacy comparative model. Contradictory to our findings, data from Shenoy, et al. suggested that secondary IOL-I is relatively safe procedure [8]. Still, visual outcomes and postoperative complications are not specific to the correction method used or the age of the patient. Several other factors such as technical surgical aspects, as well as the level of training of surgeons may play a crucial role in visual outcome [12,13].

There were no clinically or statistically significant changes observed in axial length between pre and postoperative assessments in either group; however, eye dimensions were reported to be increasing. In primary IOL-I group, this is probably associated with advanced age of patients (mean \pm SD = 67.53 \pm 48.70 months), which exceeds the age of myopic shift [2-4]. However, for secondary IOL group which underwent cataract surgery much earlier (mean \pm SD age = 5.90 \pm 3.72 months), the absence of significant myopic shift could be explained by relatively short period of follow up between cataract surgery and IOL-I, mean \pm SD period = 50.44 \pm 18.41 months.

Regardless of the method used for optical correction, cataract surgery should be done as earlier as possible, by consensus, with close monitoring of postoperative IOP and aphakia. Failure to perform cataract surgery or significant delay, especially in very young children, is associated with more severe complications like irreversible deprivation amblyopia [5,6]. Congenital cataract is responsible for a poor visual input in the first three months of life, which results in impaired maturation of the eye connections with the visual cortex that becomes irreversible, if not restored on time [14].

Conclusion

Visual outcomes including visual acuity, strabismus and myopic shift were better in primary IOL-I group (aged ≥2 years), as compared to secondary IOL-I group (aged <2 years), following congenital cataract surgery. However, poor visual outcomes in the secondary IOL=I group were mainly explained by the relatively higher prevalence of eye complications in this group. Further age-based detailed evaluation of visual acuity outcomes and myopic shift is required during the time from primary lensectomy to secondary intraocular lens implantation to draw more solid conclusions.

Accurate comparison between the two IOL-I techniques warrants age-adjusted randomized trials using a safety and efficacy model to determine the best option for optical correction with the least adverse effects in each specific age group.

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