



# Incidence of Early Onset Glaucoma after Infant Cataract Extraction With and Without Intraocular Lens Implantation

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1    ***Title:***

2    Incidence of Early Onset Glaucoma after Infant Cataract Extraction With and Without  
3    Intraocular Lens Implantation

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## ABSTRACT

**Aims:** To determine the incidence of glaucoma, with onset within one year after the date of cataract surgery (early onset) performed in the first year of life, with or without intraocular lens (IOL) implantation.

**Methods:** A retrospective review of a single surgeon's cohort from 1999 to 2006. Glaucoma onset risk, comparison of aphakic/ pseudophakic eyes and IOL type were analysed together with microcornea, persistent fetal vasculature (PFV) and age  $\leq 4$  weeks at surgery.

**Results:** Ninety-eight eyes(62 patients;mean age 2.88 months) were included with 61 eyes(36 patients) aphakic (57 planned and 4 failed implantations), and 37 eyes(26 patients) pseudophakic. At a mean follow-up of 2.51 years,15.3% (12.2% within 1 year) of all eyes, 9.8% of eyes (6.6% within 1 year) in the planned aphakic group, all 4 eyes with failed implantation and 13.5% of the pseudophakic eyes (10.8% within 1 year) developed glaucoma. Glaucoma incidence stratified by absence or presence of IOL showed no statistically significant difference, but eyes in the rigid polymethylmethacrylate group had an increased glaucoma risk compared to the Acrysof® group ( $p=0.002$ ). Microcornea, PFV and Age  $\leq 4$  weeks at surgery were not significant predictors of early onset glaucoma.

**Conclusions:** In this single surgeon study of infant cataract surgery only, age  $\leq 4$  weeks at surgery was not a predictor of early onset glaucoma. The rate of aphakic and pseudophakic early onset glaucoma was not found to be statistically different but we found a statistically different rate of glaucoma between the two IOL types which needs

further evaluation given that this is a retrospective review. Excessive surgical trauma influences incidence of glaucoma.

## INTRODUCTION

Despite advances in congenital cataract management, glaucoma after surgery remains a challenging problem.<sup>1-11</sup> Earlier surgery may give the best chance for visual rehabilitation but with a possible increased glaucoma risk. Primary IOL implantation has become increasingly common in infants but studies implying that IOL implantation may be protective against glaucoma,<sup>6-9</sup> are likely flawed by the inclusion of all ages up to 18 years, with an IOL selection bias for the older age group. Multiple surgeons with varied surgical techniques may be a further confounding factor.

Despite numerous studies<sup>3-11</sup> about aphakic/pseudophakic glaucoma, there is no consistent definition of glaucoma with intraocular pressure (IOP) threshold ranging from more than 21 mmHg to  $\geq 26$  mmHg.<sup>3,5-9,11</sup> Secondary ocular changes are only variably included in the diagnostic criteria,<sup>3-9,11</sup> while others base their diagnosis on the decision of the ophthalmologist to treat without defining glaucoma.<sup>4,8,10</sup> More recently it has been suggested that aphakic glaucoma onset may be earlier than previously suggested.<sup>10</sup>

The present study is limited to infants who underwent cataract surgery with or without IOL implantation by a single surgeon at a single centre. The aim is to determine and compare the incidence of **early onset glaucoma** in these infants.

## METHODS

All lensectomies performed in patients 1 year old or younger between 1999 and 2006 by a single surgeon (KKN) at Great Ormond Street Hospital for Children were identified by

database search. The study was approved by the Hospital institutional review board and adhered to the tenets of the Declaration of Helsinki. Exclusion criteria include pre-existing glaucoma, history of trauma, serious ocular malformation, Lowe syndrome and maternal rubella syndrome. Eyes with persistent fetal vasculature (PFV) were included. Eyes with microcornea defined as horizontal cornea diameters (HCD) <10mm, or <9.5mm in those less than 4 months of age, at the time of surgery were also included.<sup>5,12</sup>

Data extraction included patients' age at surgery, associated systemic and ocular anomalies, family history, cataract type, surgical technique, IOL implantation, type of IOL, intra- and post-operative complications. Pre- and post-operative evaluations included visual assessment, IOP, HCD and optic nerve appearance, date of glaucoma onset, length of follow-up, IOP at final follow-up, and type of glaucoma intervention. IOP was measured at every clinic visit using either Pulsair tonometer (Keeler, Windsor, UK) or Perkins hand-held tonometer (Clement Clarke, London, UK). In cases where this was not possible, examinations under anaesthesia were performed to evaluate for glaucoma.

Glaucoma was defined as a sustained rise in IOP >21mmHg OR one or more ocular signs of glaucoma (progressive optic disc cupping, increase in horizontal corneal diameter, increased myopic shift, and corneal clouding) OR both. If a child needed anaesthetic examination with or without intervention, gonioscopy was performed. Early onset glaucoma was glaucoma detected less than one year after cataract surgery.

### **Surgical technique**

Eyes with microcornea or capsular bag diameter of less than 8mm as measured using preoperative ultrasound were excluded from implantation of IOL. The operations were

performed by a single surgeon. In all cases, lensectomy was performed through two corneal incisions using automated aspiration and irrigation, followed by posterior capsulotomy and anterior vitrectomy. In cases where an IOL was implanted, a TIPP capsulorrhexis technique<sup>13,14</sup> was used for both the anterior and posterior capsulotomy. Biometry was performed at the time of surgery. Either a rigid heparin-surface-modified polymethylmethacrylate (HSM-PMMA) IOL (Pharmacia 812C) or a foldable 3-piece or 1-piece Acrysof® IOL (MA60AC or SA60AT, Alcon laboratories) was implanted. If in-the-bag implantation was not achieved the IOL would be removed and the patient left aphakic. Posterior capsulotomy and anterior vitrectomy was performed via a pars plicata approach after lens implantation except when the axial length was greater than 20mm when the lens was implanted after posterior capsulorrhexis and anterior vitrectomy via an anterior approach. No IOLs were placed in the sulcus.

### **Statistical analysis**

The risk of onset of glaucoma was modeled using Kaplan-Meier estimators, and the log rank test was used to compare the risk of glaucoma in aphakic eyes versus pseudophakic eyes. A multivariable Cox proportional hazards regression model was developed, which tested potential predictors of glaucoma: microcornea, PFV and age at the time of surgery. Model selection was based on likelihood ratio tests; these allowed determination of the relative importance of the predictors. Comparison of mean follow-up was performed using the Wilcoxon rank test. In the pseudophakic group, Fisher's Exact Test was used to compare the risk of glaucoma in the HSM-PMMA versus Acrysof® groups. All calculations were performed in R version 2.5.0 in a windows environment.<sup>15</sup> While we were interested in early onset glaucoma, statistical analysis was performed on **all** cases of

glaucoma since this cohort includes cases where risk of glaucoma is thought to be highest (i.e.  $\leq 1$  year).<sup>3,5,18</sup>

## RESULTS

A total of 98 eyes of 62 patients with a mean age of 2.88 months (range 0.33 to 12.73) at the time of surgery were included. Sixty-one eyes of 36 patients were aphakic and 37 of 26 patients received primary intraocular lens implantation. In the aphakic group the mean age was 2.00 months (range 0.33 to 7.70), and in the pseudophakic group 4.31 months (range 0.73 to 12.73). Mean follow up was 2.51 years for the entire cohort (range 0.1 to 7.84), and similar in both the aphakes (mean 2.61 yrs, range 0.1 to 7.84) and pseudophakes (mean 2.32, range 0.1 to 7.24) groups (Wilcoxon test  $p = 0.4547$ ).

In 4 cases an implant was placed in the bag, only to be removed because of posterior IOL migration. Since no IOL was placed in the sulcus these lenses were removed often with much iris manipulation. All 4 cases developed glaucoma within 14 weeks; mean onset at 1.34 months (range 0.33 to 3.27 months). This group is included in the statistical analysis of patients who had planned lensectomy without IOL but it should be noted that the cases within this group represent an unusual cohort.

The overall incidence of glaucoma was 15.3% (15 in 98 eyes, 14 patients), with 12.2% occurring within the first year. In the aphakes, 10 out of 61 eyes (16.4%, 95% CI 0.092, 27.6) developed glaucoma at a mean of 5.03 months (range 0.1 to 27.1) (13.1% within 1 year), whilst in the pseudophakes, 5 out of 37 eyes (13.5%, 95% CI 0.059, 28.0) developed glaucoma at a mean of 5.56 months (range 0.67 to 14.70) (10.8% within 1 year); there was no significant difference between both groups (Fisher's Exact Test  $p =$

0.7793). Kaplan-Meier estimates of glaucoma incidence stratified by absence or presence of IOL implantation at the time of lensectomy showed no significant difference ( $p = 0.752$ , Hazard ratio 0.84, 95% CI = 0.286, 2.47) (Figure 1). Exclusion of the 4 eyes with explantation the mean onset of glaucoma in the aphakes increases from 5.03 months to 7.49 months.

After adjusting for age at the time of surgery, Kaplan-Meier analysis of glaucoma incidence stratified by absence or presence of IOL implantation at surgery again showed no significant difference ( $p = 0.99$ , Hazards ratio 1.01, 95% CI 0.35, 2.9) if the IOL group was considered homogenous. However, of the 37 eyes that had primary IOL implantation, 12 had rigid HSM-PMMA IOL and 25 had foldable acrylic IOLs (MA60AC, 24 eyes and SA60AT, 1 eye). All 5 pseudophakic eyes which developed glaucoma had rigid HSM-PMMA IOLs and none of the eyes which had foldable acrylic IOLs were similarly affected. Comparison of HSM-PMMA vs acrylic IOLs groups using Fisher's Exact Test showed a statistically significant increased risk of glaucoma in the HSM-PMMA group ( $p = 0.002$ , Adjusted odds ratio: 37.4, 95% CI 2.46, Infinity). (See Figure 2).

Age of 4 weeks or less at the time of surgery was not found to be a significant predictor of glaucoma ( $p = 0.064$ , Hazards ratio 0.32, 95% CI 0.096, 1.07). In the aphakes, 9 eyes were considered to have microcornea, and 1 of these eyes developed glaucoma. In the pseudophakes, our selection criteria for primary implantation excluded eyes with microcornea. Ten patients had cataracts associated with PFV (6 in the aphakic group, and 4 in the pseudophakic group), and of these, 2 in the aphakic group and 1 in the

pseudophakic group developed glaucoma. However, both microcornea and PFV were not found to be significant predictors of glaucoma. (See Table 1).

Table 1. Multivariate Cox Proportional Hazards Ratio of Potential Predictors of Glaucoma

<b>Risk factor</b>	<b>Hazards Ratio</b>	<b>95% CI</b>	<b>P value</b>
Age at surgery ( $\leq 4$ weeks)	0.319	(0.096, 1.07)	0.064
Microcornea	0.469	(0.06, 3.68)	0.470
Persistent Fetal Vasculature (PFV)	2.52	(0.49, 13.12)	0.27

Of the 10 eyes with aphakic glaucoma, one eye developed pupil block glaucoma at 5 weeks post-operatively which responded to anterior vitrectomy. This eye, however, developed glaucoma 3 years later. Two eyes were on medications alone (1 to 2), but 8 eyes required further procedures for IOP control. These included diode cyclophotocoagulation and goniotomy, but two eyes had Ahmed tubes, one of whom underwent trabeculectomy prior to tube insertion.

Five pseudophakes developed glaucoma. Only one was controlled on medication alone. The remaining 4 eyes had diode cyclophotocoagulation (mean 2.25, range 2 to 3). One eye went onto a trabeculectomy and subsequently required an Ahmed tube for IOP control.

In addition, 6 eyes in the aphakic group and 1 eye in the pseudophakic group developed a transient rise in IOP requiring short-term medication in the early post-operative period. All cases resolved completely with no other sign of glaucoma and thus were not considered to have glaucoma.

Visual axis opacification (VAO) requiring surgical clearance occurred in 15 pseudophakes (40.5%) and 4 aphakes (6.6%). All 5 pseudophakic glaucoma cases had had VAO clearance, but only 1 of the aphakic glaucoma cases.

## DISCUSSION

Surgery during the first year of life is thought to increase the risk of glaucoma.<sup>3,5,18</sup> and therefore this cohort is high risk eyes for development of glaucoma. Previous studies indicate a bimodal aphakic glaucoma onset:<sup>4,11,15</sup> with early glaucoma presenting within the first year after lensectomy significantly associated with angle closure, and a late open angle glaucoma occurring much later,<sup>11,15</sup> but not all these studies were restricted to infants. The aim of our study was to look specifically at “early onset” secondary glaucoma occurring after infant cataract surgery. All our glaucoma cases had an open angle type configuration except for one aphake with pupil block. The mechanism of secondary open angle glaucoma after infant cataract surgery is unknown, but may be related to trabeculitis, release of chemical factors from the vitreous which are toxic to the trabecular meshwork,<sup>17</sup> or acquired micro-peripheral anterior synechiae.<sup>18</sup>

In our cohort all patients who had an implantation which was aborted **all** developed glaucoma **within 14 weeks** of surgery. Implantation was aborted after the IOL showed evidence of posterior migration usually through the posterior capsulorhexis. Under such circumstances we have been reluctant to place an IOL in the sulcus because of two reasons: firstly, when an IOL is placed in the ciliary sulcus, studies have shown that the haptics cause chronic inflammatory changes with peripheral anterior synechiae<sup>19</sup> and induce iris root/ trabecular meshwork changes.<sup>20</sup> Secondly, one of the few studies to

suggest that the axial growth of the pseudophakic infant eye is arrested/ retarded was one in which the IOLs were all placed in the ciliary sulcus of infant eyes.<sup>21</sup> Since all explanted eyes developed glaucoma we speculate that the protracted surgical trauma may lead to increased evidence of early onset aphakic glaucoma.

Our rate of early onset aphakic glaucoma (excluding the subgroup with IOL explantation) is 6.6% (4 of 61 eyes) which is similar to other recent work,<sup>11</sup> but these authors reported all their cases to be due to pupil block. Our rate is likely to rise the longer the follow up, but the purposes of this study were to look at early onset glaucoma.

The mean time to glaucoma diagnosis was 5.03 months (range 0.1 to 27.1) in the total aphakic group and 5.56 months (range 0.67 to 14.70) in the pseudophakic group.

Other studies looking at infants cataract surgery reported a later onset generally, but they either use criteria at IOP > 25mmHg<sup>6,11</sup> or base diagnosis on clinicians' decision to treat without further detail<sup>4</sup> or do not define any criteria.<sup>22</sup> With a relatively low threshold of 21 mmHg, and examination under anaesthesia being routinely performed when IOP measurement was not obtained in the clinic, our study is likely to detect most cases of glaucoma early.

Although some studies have shown that primary IOL implantation may prevent or reduce the incidence of glaucoma,<sup>7,8</sup> we did not find a statistically significant difference in terms of glaucoma-free survival when we compared our aphakic and pseudophakic groups in concordance with other recent work.<sup>6</sup>

A higher risk of secondary glaucoma has been found when surgery is performed early, with studies using a variable threshold of either 4 weeks,<sup>4,8</sup> 9 months,<sup>5,9</sup> or 1 year of

age.<sup>3</sup> Using a cutoff of 4 weeks, we did not show a statistically significant effect of age on the rate of early onset glaucoma. This may be due to shorter follow-up.

We did not find microcornea in itself to be a significant predictor of glaucoma in our multivariate analysis and this could be explained by selection bias, but it should be noted that the capsular bag diameter was often used to determine whether an implant could be placed or not. Microcornea has been variably shown to be associated with development of aphakic glaucoma.<sup>5,6,12,17</sup> PFV was not found to be a significant predictor of glaucoma in our series. All cases in our series were performed by a single surgeon using standard surgical techniques, which may overcome some of the compromise in the other studies where multiple surgeons were involved.<sup>4-10</sup>

Within the pseudophakic group, we found that eyes with HSM-PMMA IOL had a statistically significantly higher rate of glaucoma than the acrylic IOL group. In fact, none of the eyes in the latter group developed glaucoma during the period of follow-up. We are puzzled by this finding and again with further follow-up this may change. The retrospective nature of this study may have induced an unforeseen sampling error but nevertheless this finding is present. One-piece and three-piece foldable hydrophobic acrylic lenses have superseded the rigid one piece IOLs.<sup>23-26</sup> The mean capsular bag diameter is about 7.0 to 7.5 mm at birth and increases to about 9.0 to 9.5 mm after 2 years.<sup>27</sup> Comparison of the amount of capsulorhexis ovaling and capsular bag stretch produced by various IOLs implanted in pediatric human cadaveric eyes younger than 2 years found the greatest amount of capsular stretch/ ovaling for the rigid HSM-PMMA IOL.<sup>28</sup> We speculate that the rigid HSM-PMMA IOL vaults in order to find its resting position in the small infant capsular bag resulting in either forward optic vaulting against

the pupil causing pupil block or backward vaulting causing the haptics to push against the iris root. Since none of the pseudophakic cases had pupil block we suspect the haptics caused the iris root to be pushed forward with a possible secondary trabeculitis. While rigid single piece 12mm diameter HSM-PMMA lenses are usually no longer used in the developed countries, they are used in developing countries due to cost pressures. We advise caution when using 12mm diameter rigid IOLs in infant cataract surgery despite the limitations of our retrospective study.

Trivedi reported that for patients who underwent surgery during the first 4.5 months of their life (using hydrophobic acrylic foldable IOLs), the glaucoma incidence was 24.4% in children with pseudophakic eyes and 19% in age-matched children with aphakic eyes<sup>6</sup>. As there is no clarification regarding where the lens is placed (sulcus versus bag), it is possible that the higher incidence of glaucoma in the pseudophakic group may be related to sulcus placed implants based on the effects of sulcus placement described above.

Our study is limited in that it is a retrospective study with relatively short follow-up but we were specifically looking at early onset glaucoma. We have included eyes with follow-up as short as 0.1 years because we have eyes that developed glaucoma that early. However, it is one of the largest series of cataract surgery in infants under one year old performed by a single surgeon with identical surgical technique.

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## **LEGENDS**

Figure 1. Kaplan-Meier plot of glaucoma-free survival in aphakic eyes versus those that received primary intraocular lens implantation, as a function of time after surgery.

Figure 2. Kaplan-Meier plot of glaucoma-free survival stratified by aphakia and type of intraocular lens (Acrysof and PMMA), as a function of time after surgery.



