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# 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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21

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31

32

33 **ABSTRACT**

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

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

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

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

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

## 57 **INTRODUCTION**

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

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

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

74

## 75 **METHODS**

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

78 database search. The study was approved by the Hospital institutional review board and  
79 adhered to the tenets of the Declaration of Helsinki. Exclusion criteria include pre-  
80 existing glaucoma, history of trauma, serious ocular malformation, Lowe syndrome and  
81 maternal rubella syndrome. Eyes with persistent fetal vasculature (PFV) were included.  
82 Eyes with microcornea defined as horizontal cornea diameters (HCD) <10mm, or  
83 <9.5mm in those less than 4 months of age, at the time of surgery were also included.<sup>5,12</sup>

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

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

#### 98 **Surgical technique**

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

101 performed by a single surgeon. In all cases, lensectomy was performed through two  
102 corneal incisions using automated aspiration and irrigation, followed by posterior  
103 capsulotomy and anterior vitrectomy. In cases where an IOL was implanted, a TIPP  
104 capsulorrhexis technique<sup>13,14</sup> was used for both the anterior and posterior capsulotomy.  
105 Biometry was performed at the time of surgery. Either a rigid heparin-surface-modified  
106 polymethylmethacrylate (HSM-PMMA) IOL (Pharmacia 812C) or a foldable 3-piece or  
107 1-piece Acrysof® IOL (MA60AC or SA60AT, Alcon laboratories) was implanted. If in-  
108 the-bag implantation was not achieved the IOL would be removed and the patient left  
109 aphakic. Posterior capsulotomy and anterior vitrectomy was performed via a pars plicata  
110 approach after lens implantation except when the axial length was greater than 20mm  
111 when the lens was implanted after posterior capsulorrhexis and anterior vitrectomy via an  
112 anterior approach. No IOLs were placed in the sulcus.

### 113 **Statistical analysis**

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

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

126

## 127 **RESULTS**

128 A total of 98 eyes of 62 patients with a mean age of 2.88 months (range 0.33 to 12.73) at  
129 the time of surgery were included. Sixty-one eyes of 36 patients were aphakic and 37 of  
130 26 patients received primary intraocular lens implantation. In the aphakic group the mean  
131 age was 2.00 months (range 0.33 to 7.70), and in the pseudophakic group 4.31 months  
132 (range 0.73 to 12.73). Mean follow up was 2.51 years for the entire cohort (range 0.1 to  
133 7.84), and similar in both the aphakes (mean 2.61 yrs, range 0.1 to 7.84) and  
134 pseudophakes (mean 2.32, range 0.1 to 7.24) groups (Wilcoxon test  $p = 0.4547$ ).

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

141 The overall incidence of glaucoma was 15.3% (15 in 98 eyes, 14 patients), with  
142 12.2% occurring within the first year. In the aphakes, 10 out of 61 eyes (16.4%, 95% CI  
143 0.092, 27.6) developed glaucoma at a mean of 5.03 months (range 0.1 to 27.1) (13.1%  
144 within 1 year), whilst in the pseudophakes, 5 out of 37 eyes (13.5%, 95% CI 0.059, 28.0)  
145 developed glaucoma at a mean of 5.56 months (range 0.67 to 14.70) (10.8% within 1  
146 year); there was no significant difference between both groups (Fisher's Exact Test  $p =$



147 0.7793). Kaplan-Meier estimates of glaucoma incidence stratified by absence or  
148 presence of IOL implantation at the time of lensectomy showed no significant difference  
149 ( $p = 0.752$ , Hazard ratio 0.84, 95% CI = 0.286, 2.47) (Figure 1). Exclusion of the 4 eyes  
150 with explantation the mean onset of glaucoma in the aphakes increases from 5.03 months  
151 to 7.49 months.

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

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

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

171

172 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

173

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

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

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

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

191

## 192 **DISCUSSION**

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

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

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

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

219 The mean time to glaucoma diagnosis was 5.03 months (range 0.1 to 27.1) in the  
220 total aphakic group and 5.56 months (range 0.67 to 14.70) in the pseudophakic group.  
221 Other studies looking at infants cataract surgery reported a later onset generally, but they  
222 either use criteria at IOP > 25mmHg<sup>6,11</sup> or base diagnosis on clinicians' decision to treat  
223 without further detail<sup>4</sup> or do not define any criteria.<sup>22</sup> With a relatively low threshold of  
224 21 mmHg, and examination under anaesthesia being routinely performed when IOP  
225 measurement was not obtained in the clinic, our study is likely to detect most cases of  
226 glaucoma early.

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

231 A higher risk of secondary glaucoma has been found when surgery is performed  
232 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

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

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

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

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

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

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

275

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346        pediatric human eyes. J Cataract Refract Surg 2004;30:2183-91.

347

348    **LEGENDS**

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

351

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

354



