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## Visual Outcome Following the Reduction or Cessation of Patching Therapy After Early Unilateral Cataract Surgery

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### Abstract

**Objective**—To evaluate the impact on visual acuity of reducing or abandoning patching therapy during the first six years of life after early unilateral cataract surgery.

**Methods**—We reviewed the medical records of nine children with unilateral congenital cataracts who underwent cataract surgery when  $\leq 6$  weeks of age. All had good compliance with optical correction until 6 years of age and patching therapy until at least 12 months of age.

**Results**—The children underwent cataract surgery at a mean age of  $21.7 \pm 9.5$  days. At 12 months of age the children were patched a mean of  $6.7 \pm 2.4$  hours/day. Patching compliance declined steadily thereafter. By 6 years of age, they were only being patched a mean of  $1.7 \pm 2.0$  hours/day. Four children abandoned patching prior to the 6 year exam; the acuities improved or remained the same for three of these children, but worsened for one child by two lines.

**Conclusions**—Visual acuity remained relatively stable even when patching therapy was reduced or abandoned by children  $\leq 6$  years of age provided cataract surgery was performed during early infancy, an optical correction was consistently worn and there was good compliance with patching therapy during early childhood.

### Introduction

A number of studies have shown that good visual outcomes can be achieved in children with unilateral congenital cataracts following early cataract surgery, consistent optical correction with either a contact lens or an intraocular lens and part-time patching therapy of the fellow eye<sup>1–5</sup>; however, the amount and duration of patching therapy necessary to achieve a good visual result is not known. While some clinicians have customized patching regimens based on the visual acuities of children's aphakic eyes<sup>2,6–8</sup>, most have recommended patching the phakic eye a fixed number of hours each day.<sup>9–12</sup> In the Infant Aphakia Treatment Study, parents are asked to patch their child one hour a day per month of life until they are 8 months of age and then one-half of their waking hours ([www.sph.emory.edu/IATS](http://www.sph.emory.edu/IATS)). It is generally

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recommended that patching therapy be continued until a child is at least 6 years of age, but some investigators have recommended patching until children are 9 years of age.<sup>9–10</sup> We performed a retrospective study to determine if the age at which patching therapy was reduced or discontinued was related to the visual acuity obtained in the aphakic/pseudophakic eye.

## Methods

After obtaining approval from the respective Institutional Review Boards, we reviewed the medical records of all children treated by three pediatric ophthalmologists with a visually significant unilateral congenital cataract ( $\geq 3$  mm central opacity) who underwent cataract surgery when  $\leq 6$  weeks of age. To be included in the study children had to have: 1) a normal intraocular pressure, retina, optic disc and ciliary processes and a corneal diameter  $\geq 9$  mm in the operative eye; 2) a normal fellow eye; 3) good compliance with optical correction of the aphakic/pseudophakic eye until 6 years of age; 4)  $\geq 3$  hours/day of patching therapy as reported by the caregiver at the 12 month examination; and 5) an annual ocular examination at least until the child was 6 years of age. Children were excluded from the study if postoperatively they developed glaucoma (an elevated intraocular pressure  $>25$  mm Hg persisting for more than two weeks after topical corticosteroids were discontinued or an intraocular pressure  $>21$  mm Hg with any one of the following findings: enlargement of the cornea, asymmetrical progressive 'myopic' shift or increased optic nerve cupping) or a visual axis opacity requiring a membranectomy. Nine children qualified for the study. Data on these children was then entered on standardized case report forms that included: the inclusion criteria, the date and type of cataract surgery and postoperative complications, and clinical data on the ocular examinations performed closest to the children's birthdays at one, two, three, four, five and six years of age. The case report forms included the date of each of these examinations, the number of waking hours per day on average that parents reported that they were patching their child, the type and power of the optical correction being worn, and the child's optotype acuity including the test used to obtain the acuity measurement. The case report forms were then faxed into a database from which summaries were produced. Means and standard deviations are reported as mean  $\pm$  standard deviation.

## Results

The children underwent cataract surgery at a mean age of  $21.7 \pm 9.5$  (range, 5–34) days (Table 1). Eight children were left aphakic and initially treated with a contact lens while one child underwent primary IOL implantation (Pharmacia 811A) combined with spectacle overcorrection. Two children underwent secondary IOL implantation (Patient 8, Alcon MA60; Patient 9, Alcon SN60) when 4 and 6 years of age respectively. No serious contact lens associated complications were reported. Five patients underwent strabismus surgery. No other reoperations were performed during the follow-up period.

At the one year examination, the parents reported patching the children a mean of  $6.7 \pm 2.4$  (range 3.5 to 10) hours/day (Table 2). By the 2 year examination, the mean duration of patching had decreased on average to  $4.7 \pm 3.7$  (range 0.5 to 11) hours/day and then increased slightly at the 3 year examination  $5.2 \pm 3.1$  (range 1.5 to 11) hours/days, and gradually decline thereafter due to patching being discontinued in 4 children and markedly reduced in two children. At the 4 year examination patching averaged  $3.9 \pm 3.3$  (range 0 to 11) hours/day, at the 5 year examination,  $2.6 \pm 2.5$  (range 0 to 6) hours/day and at the 6 year examination,  $1.7 \pm 2.0$  (range 0 to 5) hours/day. Two children stopped patching between the 3 and 4 year examinations, one between the 4 and 5 year examinations and one between the 5 and 6 year examinations.

Optotype acuities were available for all of the children at the 5 and 6 year examinations and all but one of the patients at the 4 year examination (Table 3). The acuities in the fellow eyes

ranged from 20/20 to 20/25. The acuities in the aphakic/pseudophakic eyes ranged from 20/30 to 20/200 at 6 years of age. The acuity improved in the aphakic/pseudophakic eyes from the 4 to the 6 year examination for four patients, worsened for three patients and remained the same for one patient. The acuities remained the same for three patients who discontinued patching prior to the 6 year examination, but worsened for one patient (20/25 to 20/40). A much longer follow-up was available for Patient 6.

## Case Report

Patient 6 underwent a lensectomy in his left eye when 2 weeks of age. Postoperatively, his aphakia was corrected with a soft contact lens. At 12 months of age, his parents reported patching his right eye 8 hours/day. The patching was then increased to 11 hours a day for the next three years. At two years of age, he underwent a left medial rectus recession to correct an esotropia. When 4 ½ years of age, his parents reduced the patching therapy to 7 hours/day for 5 days each week. The patching was then reduced to 4 hours/day for 3 days each week when he was 5 years of age. Finally, they tapered the patching to 4 hours/day for 2 days each week when he was 6 years of age and then stopped the patching when he was 7 years of age. At 6 years of age, his Snellen acuity was 20/25 in his right eye and 20/40 in his left eye. At 7 years of age, he began wearing a rigid-gas permeable contact lens on his aphakic eye and his visual acuity improved to 20/20 in both eyes. For the next 16 years his visual acuity remained 20/20 in his aphakic eye and  $\geq 20/20$  in his phakic eye, however he never had any measurable stereopsis.

## Discussion

There was a gradual reduction in the number of hours of patching therapy reported by the parents in our study as their children became older. This is not surprising considering the difficulty of maintaining a treatment that requires so much parental involvement for so many years. In addition, four patients discontinued patching therapy entirely prior to the ocular examination closest to their sixth birthday. Despite the reduction and in some cases cessation of patching therapy in some of these children prior to the six year examination, the visual acuities were relatively stable once optotype acuity testing could be performed. Thus even though four patients discontinued patching therapy when 3–6 years of age, the visual acuities remained the same or improved in three patients and only decreased in one patient.

The optimal amount and duration of patching necessary to achieve the best visual outcomes in children following early unilateral cataract surgery is unknown. While many investigators recommend patching the fellow eye a fixed number of hours each day or a percentage of a child's waking hours, other have tried to customize patching regimens based on the visual acuity of the aphakic or pseudophakic eye. Since a subjective visual acuity cannot usually be assessed until a child is at least three years of age, customized patching regimens have generally relied on serial visual assessments using visual evoked potentials, preferential looking or fixation preferences. Beller and colleagues<sup>2</sup> prescribed patching regimens ranging from 4 to 8 hours/day based on the results of monthly visual evoked potential testing. Catalano<sup>6</sup> prescribed patching regimens ranging from 10% to 100% of a child's waking hours based on serial preferential looking testing. Lloyd and coworkers<sup>7</sup> used three different patching regimens based on interocular acuity differences using preferential looking assessed at each follow-up examination (<0.5 octaves=patching 50% of waking hours; 1–1.5 octaves= patching 75% of waking hours;  $\geq 2$  octaves= patching 100% waking hours). Finally, Brown and colleagues<sup>8</sup> customized patching regimens based on spontaneous fixation preferences or induced tropia testing. However, none of these studies addressed the issue of what age patching therapy could be discontinued without adversely affecting the visual acuity of the aphakic or pseudophakic eye?

Generally patching therapy is recommended for children with unilateral aphakia or pseudophakia following early cataract surgery until it is believed that they are no longer at risk of developing amblyopia. Parks<sup>9</sup> reported using part-time patching therapy until children were 9 years of age. Birch and Stager<sup>10</sup> reported patients were asked to patch the phakic eye 6–8 hours/day until they were at least 6 years of age, but stopped in all cases by 9 years of age. Finally, Lundvall<sup>13</sup> recommended part-time patching until children were 6–7 years of age.

Patching therapy is discontinued in most children with strabismic and anisometropic amblyopia without a recurrence of their amblyopia. Holmes and colleagues<sup>14</sup> reported a recurrence rate of only 25% in children < 8 years of age with anisometropic or strabismic amblyopia after the cessation of patching therapy. They also reported that the recurrence of amblyopia was mitigated by reducing patching therapy from 6–8 hours/day to 2 hours/day prior to discontinuing patching. One-half of the children in their study were < 6 years of age when patching therapy was terminated. They also reported that the better the visual acuity in the amblyopic eye, the more likely the amblyopia would recur.<sup>15</sup>

Amblyopia in children with unilateral congenital cataracts can arise from visual-deprivation, strabismus or anisometropia.<sup>16</sup> It is unlikely that the children in our study had visual-deprivation amblyopia since all of them underwent cataract surgery prior to 6 weeks of age and none of them developed visually significant opacities of the visual axis post-operatively. Birch<sup>17</sup> and others<sup>18–19</sup> has empirically shown that there is a latent period for visual development during the first six weeks of life. It has been hypothesized that this latent period stems from vision being subcortically mediated during the neonatal period.<sup>20</sup> As a result, infants are not believed to be at risk of developing visual deprivation amblyopia during the first six weeks of life. More likely, the patients in our study developed anisometropic or strabismic amblyopia. Anisometropic amblyopia may arise in children with unilateral aphakia or pseudophakia due to periods of non-compliance with contact lens or spectacle use or anisekonia induced by their optical correction. Strabismus is also common in children with unilateral aphakia or pseudophakia and it may have been partially responsible for the amblyopia in these children.<sup>5, 21</sup> Five of the 9 patients had strabismus severe enough to warrant strabismus surgery. Therefore, the risk of their amblyopia developing or worsening following the discontinuation of patching therapy would likely be similar to that reported by Holmes and colleagues.<sup>14</sup> It is unclear if the same risk would apply for a child with unilateral aphakia or pseudophakia whose amblyopia was principally due to visual deprivation secondary to a delay in cataract surgery beyond the first six weeks of life or visually significant opacities of the visual axis arising postoperatively.

No correlation was noted between the intensity of patching at the 12 month examination and the visual outcome when these children were 6 years of age. In fact the two children who were reported to be patched the least amount at the 12 month examination (Patients 2 and 9) had some of the best visual outcomes in their aphakic/pseudophakic eyes when 6 years of age (20/30 and 20/35). While the patient who underwent the most intensive patching regimen (Patient 6) in our study only had a visual acuity of 20/40 in his aphakic eye when 6 years of age, the visual acuity in this eye improved to 20/20 after he was fit with a rigid gas permeable contact lens when 7 years of age. While clearly the more intensive patching regimen used for Patient 6 can result in an excellent visual outcome, it is unclear whether this amount of patching is necessary to achieve a similar visual result. In addition, such an intensive patching regimen may interfere with the development and maintenance of high grade binocularity.<sup>22–23</sup>

This study has a number of limitations. First, it is a retrospective and visual acuities were not measured in a uniform manner. One site primarily used Allen pictures to measure acuity, whereas the other two sites used HOTV letters in younger children and a Snellen chart in older children. Allen acuities have been reported to overestimate visual acuity by 1.5 lines in eyes

with mild amblyopia and 2.5 lines in eyes with severe amblyopia.<sup>24</sup> Second, the sample size was small. Third, the amount of patching was based entirely on the caregiver's report at an annual examination. It would have been preferable if patching had been measured directly with an occlusion dose monitor<sup>25</sup> or if it would have been recorded daily in a diary. Finally, the visual acuities may have improved when they were older either due to refinements of their optical corrections or enhanced cognitive abilities.

It is uncertain how many hours of patching a day is necessary to achieve a good visual outcome in a child who undergoes unilateral cataract surgery during early infancy. Ideally, patching therapy should be tailored for each patient based on factors such as the age of onset and severity of the cataract, the age cataract surgery was performed, and the child's compliance with optical correction. It is also uncertain at what age patching therapy may be reduced or discontinued without inducing or worsening pre-existing amblyopia. However, our study suggests that some children who undergo early unilateral cataract surgery and are compliant with their optical correction can maintain a good visual outcome even if patching therapy is reduced or discontinued prior to their 6<sup>th</sup> birthday provided they were compliant with patching therapy during early childhood.

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**Table 1**

## Surgical and Optical Treatments

Patient #	Age at Cataract Surgery (weeks)	Optical Treatment	Additional Surgeries
1	3.7	CL	None
2	3.9	CL	None
3	4.6	CL	Strabismus
4	2.0	CL	Strabismus x 2
5	3.4	CL	Strabismus
6	2.9	CL	Strabismus
7	4.9	IOL+ Spectacles	None
8	0.7	CL	Secondary IOL
9	1.9	CL	Secondary IOL Strabismus

CL= Contact Lens

IOL= Intraocular Lens

**Table 2**

Average Waking Hours per Day Parent Reported Patching Child at Each Annual Exam

Patient #	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year
1	9.0	7.0	6.0	6.0	6.0	0
2	3.5	0.5	1.5	4.0	4.0	4.5
3	7.5	1.5	1.5	2.0	1.0	2.0
4	10.0	1.0	6.0	0	0	0
5	8.0	8.0	8.0	4.5	5.0	5.0
6	8.0	11.0	11.0	11.0	5.0	2.0
7	6.0	6.0	3.0	0	0	0
8	4.0	1.5	6.0	3.5	2.0	2.0
9	4.0	5.5	4.0	4.0	0	0



**Table 3**

Longitudinal Optotype Visual Acuities in the Aphakic/Pseudophakic Eye

Patient #	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years
1	-	-	-	20/100	20/70	20/70*
2	-	-	-	20/80	20/45	20/35
3	-	-	-	-	20/200	20/200
4	-	-	20/40	20/30*	20/25	<b>20/30</b>
5	-	-	-	20/60	20/80	<b>20/40</b>
6	-	20/60	20/60	20/30	<b>20/40</b>	<b>20/40</b>
7	-	20/25	20/30	20/25*	20/40	<b>20/40</b>
8	-	-	20/60	20/50	<b>20/70</b>	<b>20/80</b>
9	-	-	-	20/40	20/30*	<b>20/30</b>

\* Examination when caregiver reported they had discontinued patching

Snellen Acuties = bold font

HOTV acuties = italics

Allen acuties = normal font