

The Course of Moderate Amblyopia Treated With Patching in Children: Experience of the Amblyopia Treatment Study

THE PEDIATRIC EYE DISEASE INVESTIGATOR GROUP*

- **PURPOSE:** To assess the course of the response to patching treatment of moderate amblyopia and to assess factors predictive of the response in children 3 years old to younger than 7 years old.
- **DESIGN:** Multicenter, randomized clinical trial comparing patching and atropine (one of the amblyopia treatment studies).
- **METHODS:** A total of 209 children 3 years old to younger than 7 years of age with amblyopia in the range of 20/40 to 20/100 from the patching treatment arm of this trial were treated with patching of the sound eye from 6 hours per day up to all waking hours. Follow-up examinations were performed at 5 weeks, 16 weeks, and 6 months. The primary outcome measure was visual acuity in the amblyopic eye at 6 months.
- **RESULTS:** After 5 weeks of treatment, mean amblyopic eye acuity improved from baseline by 2.2 lines. For patients with baseline acuity of 20/80 or 20/100, a greater number of hours of prescribed patching was associated with greater improvement in the first 5 weeks ($P = .05$). However, this relationship was not present when baseline acuity was 20/40 to 20/60 ($P = .57$). At 6 months, visual acuity was improved from baseline by a mean of 3.1 lines, with the amount of improvement no longer related to the number of hours patching prescribed at baseline ($P = .93$). Among the 157 patients improving at least 3 lines from baseline, 15% achieved their maximum improvement by 5 weeks and 52% by 16 weeks. None of the demographic or clinical factors assessed was predictive of the response to treatment.
- **CONCLUSIONS:** In the treatment of moderate amblyopia, a beneficial effect of patching is present throughout

the age range of 3 years old to younger than 7 years old and the acuity range of 20/40 to 20/100. At 6 months, the amount of improvement appears to be similar when 6 hours of daily patching are initially prescribed vs a greater number of hours. However, when the baseline acuity is 20/80 to 20/100, a greater number of hours of prescribed patching may improve acuity faster. (Am J Ophthalmol 2003;136:620–629. © 2003 by Elsevier Inc. All rights reserved.)

PATCHING OF THE SOUND EYE HAS BEEN THE MAINSTAY of amblyopia treatment. Opinions vary on the number of hours of patching per day that should be prescribed, ranging from 1 hour to full time.^{1–6} Previous studies have suggested that the response to patching is related to age,^{7,8} type of amblyopia,^{5,7–9} and depth of amblyopia.^{7,8,10} Compliance is often cited as a major problem due to visual impairment, skin irritation, and psychosocial reasons; reported rates of compliance range widely.^{11–14}

We conducted a randomized trial comparing patching with atropine as treatments for moderate amblyopia (20/40 to 20/100) in children 3 years old to younger than 7 years old. As previously reported, we found that substantial improvement in the visual acuity of the amblyopic eye occurred with both the patching and the atropine-treatment regimens. Improvement was more rapid in the patching group, but, by 6 months, the difference in acuity between groups was small (about one third of a line) and clinically inconsequential.¹⁵ In this report, we provide additional details about the visual course of the patients assigned to the patching group and about factors predictive of response to treatment.

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METHODS

THE STUDY PROTOCOL HAS BEEN DETAILED IN PREVIOUS publications^{15,16} and is summarized herein. The study, supported through cooperative agreements with the National Eye Institute of the National Institutes of Health,

was conducted by the Pediatric Eye Disease Investigator group at 47 clinical sites. Institutional review boards approved the protocol and informed consent forms, and the parent or guardian (hereafter referred to as "parent") of each study patient gave written informed consent.

The major eligibility criteria for the trial included age <7 years and sufficient maturity to complete the study's visual acuity testing protocol (which created an effective lower age limit of approximately 3 years old), visual acuity in the amblyopic eye between 20/40 and 20/100 inclusive, inter-eye acuity difference ≥ 3 logarithm of the minimal angle of resolution lines, the presence of or a history of an amblyogenic factor meeting study-specified criteria for strabismus or anisometropia, the wearing of optimal spectacle correction for a minimum of 4 weeks at the time of enrollment, and no more than 2 months of amblyopia treatment in the previous 2 years. Each patient was randomly assigned to treatment with either patching or atropine.

At enrollment, each patient in the patching group was prescribed a minimum of 6 hours patching per day up to full-time (all, or all but 1 waking hour) at investigator discretion. If, after 4 months of treatment, the acuity in the amblyopic eye had not reached 20/30 or improved from baseline by 3 or more lines, full-time patching was prescribed (if not previously prescribed). For patients who responded to treatment at any visit (acuity 20/30 or at least a 3-line improvement from baseline), the amount of patching could be reduced at investigator discretion but was required to be at least 7 hours per week as long as the acuity in the amblyopic eye was 1 or more lines worse than the acuity in the sound eye.

Protocol-specified follow-up visits were conducted at 5 weeks, 16 weeks, and 6 months (primary outcome). The primary outcome measure was the visual acuity in the amblyopic eye at 6 months, measured with the Amblyopia Treatment Study Visual Acuity Testing Protocol.^{17,18}

Compliance with the prescribed patching treatment was assessed by having the parent maintain a calendar on which the treatment received each day was logged. The calendars were reviewed by the investigator at each follow-up visit, and an assessment of the patient's compliance with the prescribed treatment was made (excellent, 76%–100% of prescribed treatment; good, 51%–75%; fair, 26%–50%; and poor, 25% or less). An average compliance score was computed for each patient from the compliance assessment at each visit while a patient was on treatment (assigning a value of 4 for excellent, 3 for good, 2 for fair, and 1 for poor). Average scores were then used to categorize each patient's overall compliance as either excellent (>3.50), good (2.51–3.50), fair (1.51–2.50), or poor (≤ 1.50).

• **DATA ANALYSIS:** Three of the 215 patients randomized to the patching group did not meet all of the eligibility criteria and were not included in the analysis (2 had an

inter-eye acuity difference less than 3 lines, and 1 did not have a definite amblyogenic factor). Three patients who dropped out immediately after randomization and had no follow-up visits also were not included. These exclusions reduced the number of patients included in the analysis to 209.

For the analysis of visual acuity at 6 months, patients were included if they had a visual acuity measurement in the amblyopic eye within the time window of the 6-month visit, or, in the absence of such a visit, if they had a visual acuity measurement no more than 1 month before or 3 months after this window. For three patients who were switched to atropine (counter to the protocol) because of patching noncompliance, the last visual acuity score obtained before the treatment switch was used in the analysis of the 6-month acuity scores. For analysis of visual acuity at 5 weeks and 16 weeks, patients were included in the analysis if they had a visual acuity measurement within 4 weeks of the target date.

Associations between patient factors were evaluated with Kruskal-Wallis tests and chi-square tests (as indicated). The associations between patient factors and amblyopic eye visual acuity at 5 weeks and 6 months were evaluated in an analysis-of-covariance model, with the outcome visual acuity score as the dependent variable and the patient factor and baseline visual acuity as independent variables (all factors were analyzed as categorical variables except for baseline acuity and age, which were analyzed as continuous variables).

All reported *P* values are two-sided. Statistical analyses were performed using SAS statistical software (PC version 8.2, SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

THE AVERAGE AGE OF THE 209 PATIENTS WAS 5.3 YEARS; 47% were female and 81% were white. The mean visual acuity in the amblyopic eye at enrollment was approximately 20/60, with a mean difference in acuity between eyes of 4.4 lines (3 lines minimum as stipulated by the protocol). Fifty-two patients (25%) had been previously treated with patching (but not for more than 2 months in the previous 2 years, as stipulated by the protocol). Strabismus was considered the cause of the amblyopia in 82 (39%) patients, anisometropia in 79 (38%), and both strabismus and anisometropia in 48 (23%).

• **PATCHING HOURS PRESCRIBED:** The number of hours of patching prescribed at enrollment was 6 hours in 44% of patients, 8 hours in 29%, 10 hours in 7%, and 12 or more hours in 20%. The number of hours prescribed was unrelated to patient age ($P = .41$) or cause of amblyopia ($P = .33$), but was related to the baseline amblyopic eye visual acuity ($P = .004$). Among the 19 patients with an amblyopic eye acuity of 20/40, all were prescribed 6 or 8

TABLE 1. Amblyopic Eye Visual Acuity at the 5-week Exam According to Number of Hours of Patching at Baseline and Baseline Visual Acuity (n = 201)

	Number of Hours of Patching at Baseline			
	6	8	≥10	Total
Baseline Acuity 20/80 to 20/100:	n = 30	n = 19	n = 36	n = 85
5-week acuity:	%	%	%	%
≥20/80	87	95	97	93
≥20/60	73	79	92	82
≥20/50	57	63	75	66
≥20/40	37	32	53	42
≥20/30	13	11	22	16
≥20/25	0	5	8	5
≥20/20	0	5	0	1
≥20/15	0	0	0	0
Lines change from baseline* Mean (SD)	2.0 (1.7)	2.6 (1.6)	3.0 (1.4)	2.6 (1.6)
Baseline acuity 20/40 to 20/60:	n = 57	n = 41	n = 18	n = 116
5-week acuity:	%	%	%	%
≥20/50	95	95	94	95
≥20/40	89	85	83	87
≥20/30	60	68	39	59
≥20/25	28	24	11	24
≥20/20	7	2	0	4
≥20/15	0	0	0	0
Lines change from baseline* Mean (SD)	2.0 (1.0)	2.0 (1.3)	1.8 (1.0)	2.0 (1.1)

logMAR = logarithm of the minimal angle of resolution; SD = standard deviation.

* $P = .05$ for patients with baseline acuity 20/80 to 20/100 and $P = .57$ for patients with baseline acuity 20/40 to 20/60. P values are for the association between hours patching prescribed at baseline and 5-week acuity from analysis-of-covariance model with 5-week logMAR acuity score as dependent variable and hours prescribed patching and baseline logMAR acuity score as independent variables (categorical data used for hours patching, and continuous data used for baseline acuity).

hours per day of patching, whereas among the 48 patients with 20/100 amblyopic eye acuity, 26 (54%) were prescribed 6 or 8 hours of patching per day, and 22 (46%) were prescribed 10 or more hours of patching. Further details have been published on the relationship between acuity level and number of hours of patching prescribed.¹⁶

For 81% of the patients, the number of daily hours prescribed at baseline was the maximum number of hours prescribed during the 6-month follow-up period. For five (2%) patients, patching was increased during follow-up, but the maximum number of hours prescribed was less than 10 hours per day. For 32 (15%) patients who were initially prescribed 6 to 8 hours per day, patching hours were increased to 10 or more hours per day due to an inadequate response to the initial patching regimen. Thus, overall 89 (43%) of the patients were prescribed 10 or more hours of patching either initially or during follow-up, and 120 (57%) were prescribed a maximum of 8 hours per day.

• **CHANGE IN AMBLYOPIC EYE VISUAL ACUITY AT 5 WEEKS, 16 WEEKS, AND 6 MONTHS:** After 5 weeks, visual acuity was improved from baseline by a mean of 2.2 lines. For patients with baseline acuity of 20/80 or 20/100, there

was a positive association between the number of hours of patching and improvement in visual acuity (Table 1) ($P = .05$). However, this relationship was not present when baseline acuity was 20/40 to 20/60 ($P = .57$).

At 6 months, amblyopic eye visual acuity was improved from baseline by a mean of 3.1 lines (Table 2), with 79% of the eyes having an acuity of 20/30 or better and/or improvement from baseline by 3 or more lines. The amount of improvement was not related to the number of hours of patching prescribed at baseline ($P = .93$). Although the number of lines of improvement in acuity was greater with worse baseline acuity, the proportion of patients reaching 20/25 or better acuity was lower when the baseline acuity was worse (Table 3). Among patients with baseline acuity of 20/80 to 20/100, 20% had a 6-month acuity of 20/25 or better compared with 56% in patients with baseline acuity of 20/40 to 20/60 ($P < .001$).

Figure 1 shows the amount of improvement from baseline seen at 5 weeks, 16 weeks, and 6 months according to the baseline acuity and the number of hours of prescribed patching. It can be seen that for most patients much of the improvement seen at 6 months was present at 5 weeks. Among the 157 patients who improved 3 or more lines

TABLE 2. Amblyopic Eye Visual Acuity at 6-Month Exam According to Number of Hours of Patching Prescribed at Baseline (n = 204)

Hours of Patching Prescribed at Baseline	Overall		Baseline Acuity 20/80 to 20/100		Baseline Acuity 20/40 to 20/60	
	n	Mean Lines Change From Baseline	n	Mean Lines Change From Baseline	n	Mean Lines Change From Baseline
Overall	204	3.1	86	3.6	118	2.8
6 hours	91	3.1	30	3.4	61	2.9
8 hours	58	3.1	20	3.6	38	2.8
10 or more hours	55	3.3	36	3.8	19	2.3
P value*		.93		.65		.15

*P value for the association between hours patching prescribed at baseline and 6-month acuity from analysis-of-covariance model with 6-month logMAR acuity score as dependent variable and hours prescribed patching and baseline logMAR acuity score as independent variables (categorical for hours patching, and continuous for baseline acuity).

TABLE 3. Amblyopic Eye Visual Acuity at 6 Months According to Baseline Acuity (n = 204)

	Baseline Amblyopic Eye Acuity					Overall n = 204
	20/100 n = 46	20/80 n = 40	20/60 n = 55	20/50 n = 45	20/40 n = 18	
6-month amblyopic eye acuity	%	%	%	%	%	%
≥20/100	93					99
≥20/80	91	100				98
≥20/60	85	95	95			94
≥20/50	76	95	95	100		92
≥20/40	63	80	87	93	100	83
≥20/30	28	53	73	80	100	63
≥20/25	15	25	40	67	78	41
≥20/20	7	15	7	29	33	16
≥20/15	0	3	2	4	11	3
Lines change from baseline to 6 months						
Mean (SD)	3.6 (2.0)	3.7 (1.6)	3.0 (1.5)	2.7 (1.3)	2.2 (0.9)	3.1 (1.6)

SD = standard deviation.

from baseline during the 6-month period and completed the three protocol-specified follow-up visits, on average, 58% of the maximum attained improvement had occurred by the 5-week visit and 81% by the 16-week visit (Table 4); 15% of patients improving at least 3 lines from baseline reached their best acuity by 5 weeks and 52% by 16 weeks.

• **FACTORS ASSOCIATED WITH IMPROVEMENT IN AMBLYOPIC EYE VISUAL ACUITY:** At 6 months, the number of lines of improvement in acuity from baseline was greater when the baseline acuity was 20/80 to 20/100 than when it was 20/40 to 20/60 (mean lines of improvement 3.6 vs 2.8, $P < .001$). The amount of improvement seen at 6 months was not related to any other of the demographic or clinical factors that were assessed (Table 5). Similar improvement was seen across the age range of 3 to <7 years old and for both strabismic and anisometropic amblyopia. Assessment of the 5-week acuity data showed a

similar lack of association of baseline factors with the improvement in acuity from baseline (data not shown).

Patients whose compliance was judged to be good or excellent showed greater improvement than did patients judged to have poor or fair compliance. At the 5-week visit, the mean improvement from baseline was 2.3 lines in the 175 patients with good or excellent compliance compared with 1.8 lines in the 26 patients with poor or fair compliance ($P = .01$). At 6 months, the mean improvement from baseline was 3.3 lines in the 168 patients with good or excellent estimation of compliance, compared with 2.2 lines in the 36 patients with poor or fair compliance ($P = < 0.001$).

DISCUSSION

IN TREATING MODERATE AMBLYOPIA IN CHILDREN 3 TO younger than 7 years old, patching of the sound eye for 6

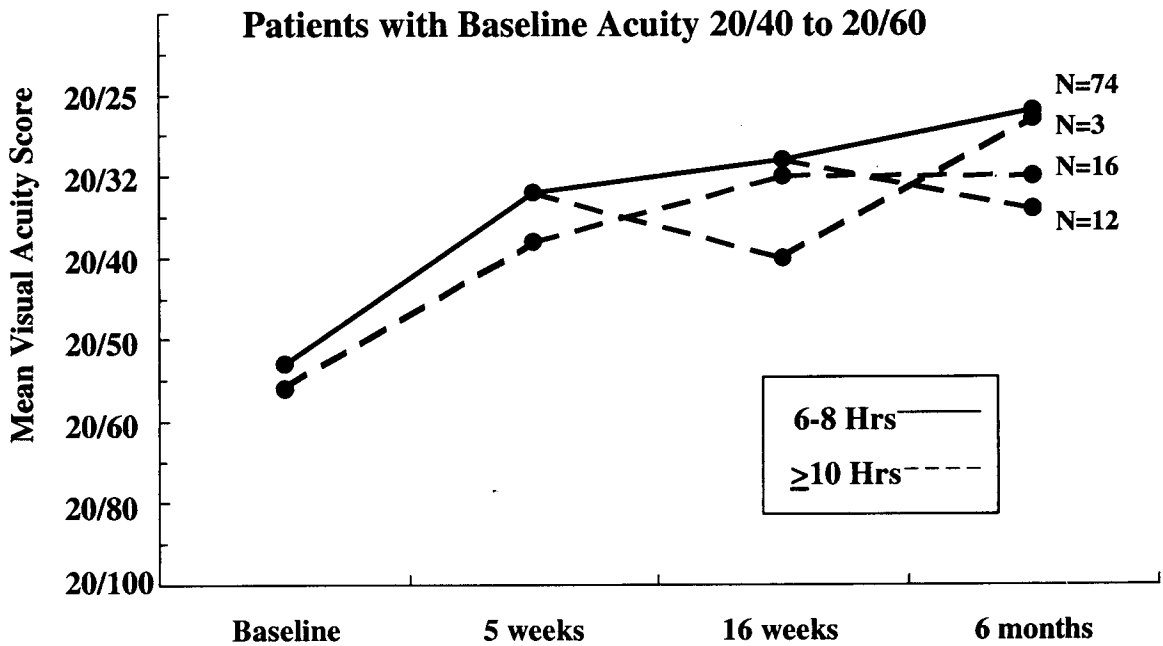
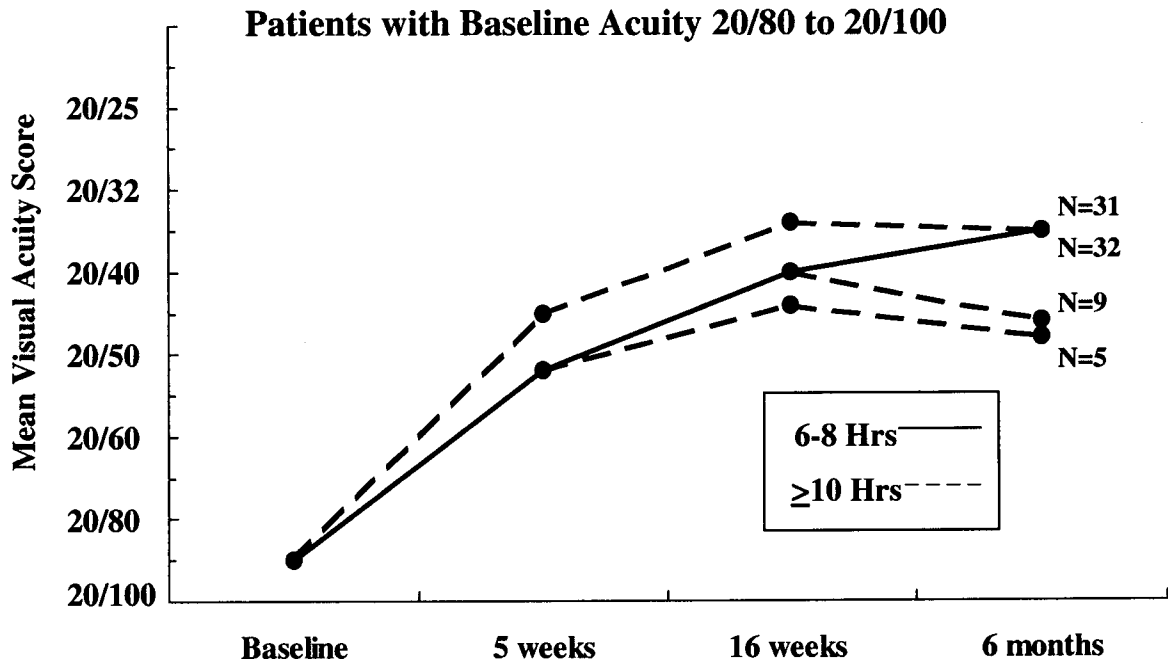


FIGURE 1. Mean amblyopic eye visual acuity at 5 weeks, 16 weeks, and 6 months according to baseline visual acuity and hours of patching prescribed at baseline and follow-up. Solid lines indicate follow-up intervals during which patients were prescribed 6 to 8 hours of patching, whereas the dashed lines indicate follow-up intervals during which patients were prescribed 10 or more hours of patching. At each follow-up interval, the patients who have had their prescribed hours increased to 10 or more are identified by the new dashed line arising from the solid line.

TABLE 4. Time Course of Attaining Best Amblyopic Eye Visual Acuity Among Patients Who Responded to Treatment (n = 157)*

	Baseline Acuity 20/40–20/60 n = 82	Baseline Acuity 20/80–20/100 n = 75	Overall n = 157
Mean percentage of maximum 6-month improvement achieved per patient by each visit			
5 weeks	59	57	58
16 weeks	76	86	81
Percentage of patients achieving maximum 6-month improvement by each visit			
5 weeks	15	15	15
16 weeks	45	60	52
*Includes patients: 1) whose amblyopic eye improved from baseline by 3 or more lines at any visit during the 6-month period, and 2) who completed the 5-week, 16-week, and 6-month visits.			

or more hours per day improved amblyopic eye visual acuity an average of 3.1 lines. Visual acuity of 20/30 or better and/or improvement from baseline by 3 or more lines was achieved by 79% of the patients. Among the patients improving at least 3 lines from baseline, 15% reached their maximum response by 5 weeks and 52% by 16 weeks. Improvement was seen across the acuity range of 20/40 to 20/100, and there was no apparent effect of age on the response to treatment.

We did not find that initially prescribing a greater number of hours of daily patching produced a better outcome at 6 months. Rather, the 6-month outcome was unrelated to the number of hours of patching initially prescribed, being similar in patients prescribed 6 or 8 hours per day and in patients prescribed 10 or more hours. However, during the initial 5 weeks of treatment, among patients with baseline amblyopic eye acuity of 20/80 to 20/100, patients who were prescribed 10 or more hours of daily patching showed greater improvement than did patients prescribed fewer hours. This dose-response relationship was not seen when the baseline acuity was 20/40 to 20/60. Because the number of hours of patching was prescribed at investigator discretion rather than being determined through randomization, our analyses of outcome based on the number of hours of prescribed patching should not be considered definitive. To address this important dose-response issue, we are currently conducting a randomized trial to compare 2 hours and 6 hours of daily patching for moderate amblyopia and 6 hours and all waking hours of daily patching for severe amblyopia.

Within the age range of 3 to younger than 7 years old, our results do not support the notion that treatment of moderate amblyopia is less successful with increased age. This premise has been attributed to both reduced compliance and reduced cortical plasticity in older children,

although it is not well-supported in previous literature. Several studies containing large numbers of patients did not reveal an age effect in children of a comparable age range to our study.^{9,10,19} A pooled analysis of 961 patients from 23 studies reported that age was related to treatment outcome; however, because the patients ranged from 0 to 53 years old and information was not given on whether this age effect was present within 3- to 6-year-olds, this finding cannot be compared with our results.⁷

We found that the response to patching was similar when the amblyopia was due to anisometropia, strabismus, or both combined. This finding differs from that of two previous studies that suggested the outcome is best with anisometropia, intermediate with strabismus, and worse when both are combined^{9,10} and from that of two studies that reported successful outcomes most commonly with strabismic amblyopia.^{7,8}

Similar to most previous studies, our study, by necessity, used imprecise methods to assess compliance. Although we found, also similar to previous studies,^{13,20} that the outcome was related to the clinician's judgment of compliance, our results must be viewed with caution because the clinician made the compliance assessment based on parental report and with knowledge of the visual acuity. A valid assessment of compliance and the dose effect from actual episodes of patching must await the widespread availability of occlusion dose monitoring devices.^{21–24} A recent pilot study of 14 children assessed compliance with an objective "Occlusion Dose Monitor" and found that children with poor compliance had significantly less acuity improvement than those with good compliance.²⁴

Patching is an effective treatment for moderate amblyopia in the age range of 3 to younger than 7 years of age. Within this age range, neither the age at initiation of therapy nor the cause of amblyopia affects the outcome of

TABLE 5. Association of Demographic and Clinical Factors With Change in Amblyopic Eye Acuity From Baseline to 6 Months

Characteristics	n	Mean Baseline Visual Acuity logMAR	Mean Lines Change From Baseline	P Value*
Overall	204		3.4	
Gender				.91
Male	106	.52	3.1	
Female	98	.53	3.1	
Race				.84
White	164	.53	3.1	
Other	40	.51	3.1	
Age (Yrs)				.93
<4	33	.57	3.3	
4 to <5	40	.54	3.1	
5 to <6	63	.52	3.2	
6 to <7	68	.50	3.0	
Baseline amblyopic eye acuity				<.001 [†]
20/80 to 20/100	86	.65	3.6	
20/40 to 20/60	118	.43	2.8	
Cause of amblyopia				.75
Strabismus	79	.51	3.0	
Anisometropia	79	.51	3.2	
Strabismus and anisometropia	46	.57	3.3	
Prior therapy for amblyopia				.65
Yes	54	.53	3.2	
No	150	.52	3.1	

*Unless otherwise indicated, *P* value for the association between patient factor and 6-month acuity from analysis-of-covariance model with 6-month logMAR acuity score as dependent variable and patient factor with baseline logMAR acuity score as independent variables (continuous for baseline acuity and age); [†]*P* value for the association between baseline acuity and 6-month acuity from linear regression model with 6-month logMAR acuity score as dependent variable and baseline logMAR acuity score as independent variable.

treatment. At 6 months, the amount of improvement appears to be similar when 6 hours of daily patching are initially prescribed vs a greater number of hours. However, when the baseline acuity is 20/80 to 20/100, a greater number of hours of prescribed patching may improve acuity faster.

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APPENDIX

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THE PEDIATRIC EYE DISEASE INVESTIGATOR GROUP

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Nashville, Tennessee - Vanderbilt Eye Center (13): Sean Donahue (I); Cindy Foss (C); Julie A. Ozier (C); Ronald J. Biernacki (V); Evelyn Tomlinson (V)

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Atlanta, Georgia - The Emory Eye Center (7): Scott R. Lambert (I); Lucy Yang (C); Alexander T. Elliott (C); Nicole Fallaha (V)

St. Louis, Missouri - Cardinal Glennon Children's Hospital (6): Oscar A. Cruz (I); Bradley V. Davitt (I); Susan A. Havertape (C); Emily A. Miyazaki (C); Molly B. Bosch (C)

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