A Randomized Pilot Study of Near Activities Versus Non-Near Activities During Patching Therapy for Amblyopia

The Pediatric Eye Disease Investigator Group*

Background: To plan a future randomized clinical trial, we conducted a pilot study to determine whether children randomized to near or non-near activities would perform prescribed activities. A secondary aim was to obtain a preliminary estimate of the effect of near versus non-near activities on amblyopic eye visual acuity, when combined with 2 hours of daily patching. ***Methods:*** Sixty-four children, 3 to less than 7 years of age, with anisometropic, strabismic, or combined amblyopia (20/40 to 20/400) were randomly assigned to receive either 2 hours of daily patching *with* near activities or 2 hours of daily patching *without* near activities. Parents completed daily calendars for 4 weeks recording the activities performed while patched and received a weekly telephone call in which they were asked to describe the activities performed during the previous 2 hours of patching. Visual acuity was assessed at 4 weeks. ***Results:*** The children assigned to near visual activities performed more near activities than those assigned to non-near activities (by calendars, mean 1.6 ± 0.5 hours versus 0.2 ± 0.2 hours daily, $P < 0.001$; by telephone interviews, 1.6 ± 0.4 hours versus 0.4 ± 0.5 hours daily, $P < 0.001$). After 4 weeks of treatment, there was a suggestion of greater improvement in amblyopic eye visual acuity in those assigned to near visual activities (mean 2.6 lines versus 1.6 lines, $P = 0.07$). The treatment group difference in visual acuity was present for patients with severe amblyopia but not moderate amblyopia. ***Conclusions:*** Children patched and instructed to perform near activities for amblyopia spent more time performing those near activities than children who were instructed to perform non-near activities. Our results suggest that performing near activities while patched may be beneficial in treating amblyopia. Based on our data, a formal randomized amblyopia treatment trial of patching with and without near activities is both feasible and desirable. (J AAPOS 2005;9:129-136)

In previous randomized studies of patching regimes for amblyopia conducted by the Pediatric Eye Disease Investigator Group,[1,2] near visual activities were incorporated into each of the prescribed treatment regimes. Although different regimes of patching, combined with near visual activities, were successful in improving visual acuity in most children,[1,2] it is unclear whether concurrent near visual activities enhanced the effect of patching.

Others have described the prescription of near activities, or activities requiring hand–eye coordination, during patching for amblyopia. Among many case series, Francois and James[3] and Callahan and Berry[4] incorporated tracing pictures or completing puzzles into their treatment for amblyopia. Von Noorden and colleagues[5] described coloring small symbols on exercise sheets for 1 hour a day during occlusion in children aged 7 to 16 years. Watson and colleagues[6] also described playing a visually demanding game while patched. None of these regimes of near activities during occlusion have been rigorously studied using randomized control trial methods, with masking and standardization of visual acuity assessment.

To plan a future randomized trial of patching with near activities versus patching without near activities, we conducted a randomized multicenter pilot study to determine the extent to which children assigned to near or non-near activities would perform the prescribed activities. We also designed the present study to provide a preliminary estimate of the effect of patching 2 hours a day with and without near activities on amblyopic eye visual acuity after 4 weeks of treatment. We planned to use these data to design a future prospective randomized trial.

SUBJECTS AND METHODS

The study was supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health and was conducted by the Pediatric Eye Disease Investigator Group[7] at 16 clinical sites. The protocol and informed consent forms were approved by institutional review boards, and the parent or guardian (referred to

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subsequently as "parent") of each study patient gave written informed consent.

Patient Selection

Patients were enrolled for a fixed time period, with a preset maximum of 80 subjects. Eligibility criteria for the trial included the following: eye-care provider intends to prescribe 2 hours of daily patching; patient age 3 to less than 7 years; visual acuity in the amblyopic eye between 20/40 and 20/400 inclusive (measured using the ATS visual acuity testing protocol with single-surrounded HOTV optotypes)[8]; sound eye acuity 20/40 or better; at least 3 logMAR levels interocular difference; the presence or history of a strabismic or anisometropic amblyogenic factor; no amblyopia treatment other than spectacles in the past month; and no more than 1 month of amblyopia treatment, other than spectacles, in the past 6 months.

Treatment Protocols

All parents were instructed to patch the sound eye of their child for 2 hours per day. In addition, each patient was randomly assigned with equal probability to either near visual activities or non-near visual activities during the 2 hours of prescribed patching. Randomization was accomplished on the study's web site using a permuted-blocks design.

Following their group assignment, instruction sheets were given to the parent listing examples of "near" or "non-near" activities. Parents of children assigned to near activities were instructed to direct their child to do tasks that specifically required up-close eye–hand coordination. Patients assigned to "non-near" activities were instructed to perform activities "that do not require up-close eye–hand coordination." Examples of near activities and non-near activities performed by the children when patched are given in Table 1. It was recognized that there might be some disagreement regarding whether specific activities might be classified as "near" or "non-near," but decisions were made by a consensus of the investigators.

TABLE 1. Classification of activities recorded on the calendars as "Near" and "Non-near" in both treatment groups

	Number of Times Reported	Total Time Spent (Hours)
Near activities		
Art/crafts	383	331
Board games/puzzles/card games	285	228
Computer/video game	253	246
Writing/reading/activity books	226	152
Blocks/marbles/dominoes	93	68
Homework	76	54
Dolls/action figures	66	54
Cars	61	32
Near activities category	32	36
Sorting/stringing beads	17	16
Lite Brite™	14	9
Stacking coins	4	5
Tying shoes	3	1
Picking fruit	1	2
Total	1514	1234
Non-near activities		
Television	604	502
Eating	280	127
General outdoor play	156	145
General indoor play	142	126
Active/physical games	127	106
Errands/car rides	102	105
Chores	90	40
Visiting/playing with friends/family	67	60
Playing	55	49
Playing ball	45	20
Playing with toys	38	30
Making food	26	14
Outdoor events/locations	20	29
Make-believe games	20	18
Grooming	18	7
Listening/singing	17	10
Dressing	12	3
Riding bike	8	5
Counting	8	4
Indoor events/locations	4	7
Remote control toys	3	1
Total	1842	1408

Calendars and Telephone Interviews

To collect data on activities performed when patched, each family was given calendars to complete each day. Parents were instructed to record the number of hours patched and the activities performed while patched. Each calendar covered 7 days, so each family received four calendars. Two different types of calendar were used and evaluated: (1) free-form, where the parent simply listed the activities with the corresponding duration in minutes and (2) categorized, where the parent was instructed to record the duration of each activity in minutes for one of five categories (near activities requiring eye–hand coordination, TV, general outdoor play, general indoor play not including activities that require up-close eye–hand coordination, other to be specified). Patients were randomized to either free-form calendars for the first 2 weeks and then categorized calendars for the second 2 weeks or vice versa. Examples of each type of completed calendar were given to the parent at the start of the study. Parents were instructed to mail calendars to the coordinating center in prestamped addressed envelopes at the end of each week of the study. One phone call per week was planned for each family. The phone call was conducted by coordinating center personnel. The phone call consisted of a scripted interview, recording the activities and duration of those activities during the last 2-hour patching period, either earlier that day or on the previous day.

Follow-Up Examinations

A visual acuity outcome visit was conducted at 4 weeks, with a planned window of 4 to 5 weeks. At the baseline visit and at the visual acuity outcome visit, acuity was

measured in each eye using the ATS visual acuity testing protocol[8] administered by a study-certified vision tester using the Electronic Visual Acuity Tester.[9]

Statistical Methods

All recorded activities were classified by data center personnel as "near" or "non-near" without reference to treatment group (Table 1). For each patient, the mean number of hours spent in near visual activities for each day patched was calculated from all calendars for that patient. For all patients within each treatment group (near versus non-near), the mean of the individual patient means was then calculated, yielding a group mean hours per day of near activities. The difference in means between the near and non-near groups was evaluated using a *t*-test.

Similarly for the phone interview data, the mean number of hours spent in near activities was determined for each patient from all the completed telephone interviews. The mean for each treatment group (near versus non-near) was then compared using a *t*-test.

Differences in the completion of calendars and phone calls between treatment groups were evaluated with Wilcoxon tests for continuous variables, as indicated. Weekly calendars were defined as "complete" if they had at least one activity entry on each of the 7 days. "Partially complete" was defined as at least one day with activity data, but less than 7 days. Identical analyses were also performed considering partially complete calendars as either complete or incomplete.

To investigate a potential effect of the treatment group (near versus non-near) on the number of hours patched, the total hours of reported patching per patient and mean hours of patching per day per patient were calculated and compared between groups. In 48 of 1372 (3%) days, the number of hours patched was missing but could be imputed from the total duration of activities recorded while patched. The calculation of mean hours of patching performed per day per patient was calculated the following three ways: (1) excluding calendars that were not received and excluding missing days; (2) excluding calendars that were not received, but assigning "zero hours" to days that were missing in incomplete calendars; and (3) assigning "zero hours" to all missing calendars and missing days.

The relationship between activities recorded on calendars and reported on phone interviews was explored using data from all days where there was both a completed phone call and a completed corresponding entry on the calendar. The number of hours spent in near visual activities was compared between telephone interviews and calendars, without respect to treatment group, in a scatter plot and by calculating an intraclass correlation coefficient.

The difference in mean change in visual acuity from baseline to outcome examination, between near and non-near treatment groups, was evaluated with a *t*-test.

TABLE 2. Baseline characteristics of each treatment group

	Overall (N = 64) *n* (%)	Near (N = 32) *n* (%)	Non-Near (N = 32) *n* (%)
Gender: Female	28 (44)	16 (50)	12 (38)
Age (years)			
<4	6 (9)	3 (9)	3 (9)
4–<5	19 (30)	12 (38)	7 (22)
5–<6	24 (38)	12 (38)	12 (38)
6–<7	15 (23)	5 (16)	10 (31)
Mean (SD)	5.2 (1.0)	5.0 (1.0)	5.4 (1.0)
Prior treatment for amblyopia			
None	56 (88)	29 (91)	27 (84)
Cause of amblyopia			
Strabismus	23 (36)	13 (41)	10 (31)
Anisometropia	20 (31)	5 (16)	15 (47)
Strabismus and anisometropia	21 (33)	14 (44)	7 (22)
Distance visual acuity amblyopic eye			
20/400	3 (5)	2 (6)	1 (3)
20/320	4 (6)	3 (9)	1 (3)
20/250	3 (5)	1 (3)	2 (6)
20/200	2 (3)	1 (3)	1 (3)
20/160	2 (3)	0	2 (6)
20/125	4 (6)	1 (3)	3 (9)
20/100	7 (11)	6 (19)	1 (3)
20/80	11 (17)	3 (9)	8 (25)
20/63	14 (22)	7 (22)	7 (22)
20/50	7 (11)	3 (9)	4 (13)
20/40	7 (11)	5 (16)	2 (6)
Mean (SD) logMAR	0.66 (0.29)	0.67 (0.31)	0.66 (0.26)

All reported *P* values are two-tailed. Analyses were conducted using SAS version 8.2 (SAS Institute, Cary, NC).

RESULTS

Between August 2003 and January 2004, 64 patients entered the randomized trial, with 32 assigned to the near activity group and 32 assigned to the non-near activity group. The number of patients enrolled per site at the 16 sites ranged from 1 to 18 (median = 3). The average age of the patients was 5.2 years and 44% were female. The mean visual acuity in the amblyopic eye at enrollment was 0.66 logMAR (approximately 20/100+). Table 2 provides the baseline characteristics of each treatment group.

Calendar and Phone Call Completion

Twenty-nine of 32 (91%) patients in the near group and 26 of 32 (81%) patients in the non-near group completed at least part of one calendar to yield primary outcome data on the mean number of hours per day spent in near visual activities ($P = 0.31$, Wilcoxon rank-sum test, Table 3). Twenty (63%) patients in the near group, and 18 (56%) of the non-near group, completed all four calendars (Table 3). There was also no difference between treatment groups (near versus non-

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TABLE 3. Calendar and phone call completion

	Near (32 patients) *n* (%)	Non-near (32 patients) *n* (%)	*P* Value Wilcoxon rank-sum test
Number of calendars completed (partial completion [eg, 3 of 7 days] treated as complete)			
0	3 (9)	6 (19)	$P = 0.31$
1	1 (3)	3 (9)	
2	1 (3)	1 (3)	
3	4 (13)	2 (6)	
4	23 (72)	20 (63)	
Number of calendars completed (partial completion treated as incomplete)			
0	5 (16)	6 (19)	$P = 0.52$
1	1 (3)	3 (9)	
2	0 (0)	1 (3)	
3	6 (19)	4 (13)	
4	20 (63)	18 (56)	
Median (quartiles) calendar days completed*	28 (21, 28)	28 (7, 28)	$P = 0.41$
Number of phone calls completed			
0	6 (19)	6 (19)	$P = 0.91$
1	4 (13)	7 (22)	
2	7 (22)	3 (9)	
3	8 (25)	9 (28)	
4	7 (22)	7 (22)	

*Maximum of 28 per patient, 896 per group.

near) in the total number of calendar days completed (median 28 days, quartiles 21 and 28, in the near group versus median 28 days, quartiles 7 and 28, in the non-near group, $P = 0.41$, Table 3).

There was no difference between groups in the number of telephone interviews completed. In both the near and the non-near group, 26 of 32 (81%) patients completed at least one of the four scheduled telephone interviews during the 4-week study period ($P = 0.91$, Wilcoxon rank-sum test, Table 3).

Hours Spent in Near Visual Activities

Based on calendar entries, the mean number of hours per day spent in near visual activities was significantly greater in the near group than the non-near group (1.6 ± 0.5 hours versus 0.2 ± 0.2 hours, $P < 0.001$ from *t*-test, Table 4).

Based on telephone interviews, the mean number of hours per day spent in near visual activities was significantly greater in the near group than the non-near group (1.6 ± 0.4 hours versus 0.4 ± 0.5 hours, $P < 0.001$ from *t*-test, Table 4).

Effect of Near versus Non-Near Activities on Patching Hours

Based on calendar entries, the total number of hours patched per patient during the 28-day study period was similar in the near and non-near groups (mean 49.7 ± 11.1 hour versus 47.1 ± 14.7 hours, $P = 0.45$). The mean hours patched per day per patient were also similar between groups (2.0 ± 0.2 versus 1.9 ± 0.2 hours, $P = 0.60$), when only using days with recorded data. Similar results were found when "zero hours" was assigned to days with missing data in otherwise complete calendars and when assigning zero hours to all missing days and missing calendars (data not shown).

Agreement between Calendars and Telephone Interviews

Of 256 possible telephone interviews, 138 were completed, and of those, 108 had a corresponding entry in a calendar. Figure 1 shows the distribution of hours spent in near visual acuities by calendar and phone call. Overall there was good agreement between calendars and telephone interviews, with an intraclass correlation coefficient = 0.78. This analysis was somewhat limited by the missing calendars and incomplete phone calls. Regarding time spent in near activities recorded on calendars and reported by phone interviews, 75 of 108 (69%) corresponding pairs were within 15 minutes of each other (Figure 1).

Comparison of Free-Form and Categorized Calendars

The extent of completion was similar between the two types of calendar (median 14 completed days, quartiles 7, 14, in both groups, $P = 0.79$, Wilcoxon signed-rank test).

The categorized calendar was designed such that the parent was instructed to write in the time spent in one or more of five categories and not list the activities performed. Nevertheless 48 of 51 (94%) patients with at least one categorized calendar erroneously recorded specific activities on the categorized calendars at least once, using the categorized calendar as a free-form calendar. Of note, 28 (58%) of these parents, who wrote in the specific activity on the categorized calendar, misclassified the activity at least once, for example, recording a near activity under "general outdoor play."

Effect of Near and Non-Near Activities on Amblyopic Eye Visual Acuity at 4 weeks

Of 64 patients, 58 (91%) completed the 4-week visual acuity outcome visit: 30 (94%) in the near group and 28 (88%) in the non-near group. The visit was completed at a median of 5 weeks (quartiles 4 and 6, range 2 to 23 weeks). There was no difference in the timing of the visual acuity outcome visit between groups ($P = 0.84$, Wilcoxon rank-sum test).

Although our study was not designed to have sufficient statistical power, or be of sufficient duration, to definitively address visual acuity outcome, there was a suggestion of a treatment effect. Visual acuity outcome data in the near group suggested a better mean visual acuity at 4 weeks, and a greater number of lines of improvement, than

TABLE 4 Hours spent in near activities by assignment to near or non-near group

	Activity Group		*P*
	Near	**Non-Near**	**Value***
All calendars	(*N* = 29 patients)	(*N* = 26 patients)	
Median of mean hours for each patient	1.6	0.1	
(quartiles)	(1.4, 1.9)	(0, 0.3)	
[range]	[0.3, 2.0]	[0, 0.7]	
Mean of mean hours for each patient (SD)	1.6 (0.5)	0.2 (0.2)	
(95% CI)	(1.4, 1.7)	(0.1, 0.2)	
Difference† (95% CI)	1.4 (1.2, 1.6)		<0.001
Telephone interviews	(*N* = 26 patients)	(*N* = 26 patients)	
Median of means for each patient	1.6	0.1	
(Quartiles)	(1.3, 2.0)	(0, 0.7)	
[Range]	[0, 2.1]	[0, 1.3]	
Mean of means for each patient (SD)	1.6 (0.4)	0.4 (0.5)	
(95% CI)	(1.4, 1.8)	(0.2, 0.6)	
Difference† (95% CI)	1.2 (0.9, 1.5)		<0.001

**P* value for difference in means between activity groups from *t* test.
†Difference between near activity group and non-near activity group. Positive difference indicates that the mean number of hours of near activities per day patched was, on average, greater in the near activities group than the non-near activity group.

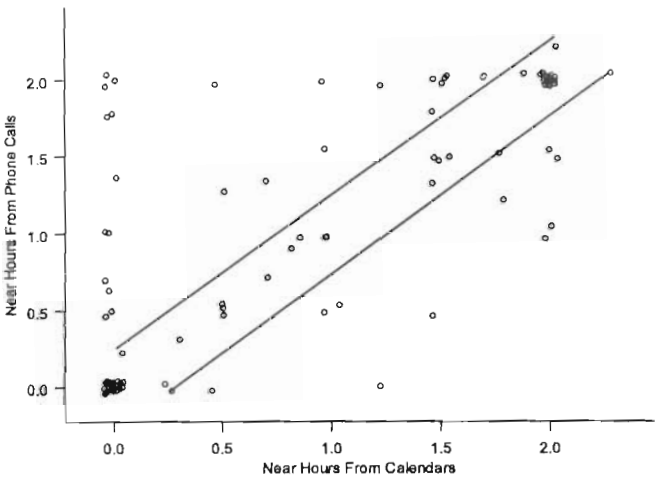

FIG 1. Comparison of calendars and telephone interviews. Scatter plot of calendar versus phone call hours spent on near activities for *N* = 108 matching dates of patching. (Lines correspond to agreement within 15 minutes.)

the non-near group (mean 2.6 versus 1.6 lines, Table 5, $P = 0.07$, *t*-test).

In an exploratory analysis of the effect of baseline visual acuity on the near versus non-near effect, the difference between treatment groups was seen in the patients with severe amblyopia (20/100 or worse) but not in those with moderate amblyopia (Figure 2). At the 4-week visit, the 13 patients with severe amblyopia in the near activities group improved by a mean of 3.7 ± 2.5 logMAR levels, compared with a mean improvement of 1.2 ± 2.3 logMAR levels in the 11 patients with severe amblyopia in the non-near group ($P = 0.02$, t-test). In contrast, the patients with moderate amblyopia in the near activities group improved by a similar amount to those in the non-near group ($n = 17$ in each group, mean ± SD 1.7 ± 1.4 versus 1.9 ± 1.2 logMAR levels, $P = 0.60$, *t*-test).

DISCUSSION

In this randomized multicenter pilot study, we compared the activities amblyopic children performed while patched, when instructed to perform either near activities or non-near activities. We found that children who were assigned to near activities when patched did indeed spend more time performing those near activities than children who were instructed to perform non-near activities. The results need to be viewed in the context of a research study and may not be generalizable to usual patient care. The patients received more intensive instructions on the type of activities to perform while patching and received weekly phone calls to monitor compliance.

Our present pilot study has provided data on the design of a calendar that might be used in future studies of activities while patched. The categorized calendar was sometimes used by parents as a free-form calendar with frequent misclassifications of activities. This suggests that even when the categorized calendar was used correctly, it may have been prone to error in the classification of activities. Asking parents to list each activity with its corresponding duration, on a free form calendar, may be less prone to error.

Although there was good agreement overall between calendars and telephone interviews, examples of disagreement are of interest. It is not clear why a calendar would indicate no near activities, while the telephone interview corresponding to that day would indicate 2 hours of near activities. It is possible that, in some cases, the calendar was completed several days after the day in question and that the parent was confused as to which day the calendar referred. It is also possible that a different parent completed the calendar and conducted the telephone inter-

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TABLE 5 Effect of near versus non-near activities on amblyopic eye visual acuity at 4 weeks

	Near (N = 30)	Non-Near (N = 28)
LogMAR levels change from baseline to 4-week visit	n (%)	
−2	0	1 (4)
−1	0	2 (7)
0	3 (10)	3 (11)
+1	9 (30)	9 (32)
+2	7 (23)	4 (14)
+3	3 (10)	4 (14)
+4	2 (7)	4 (14)
+5	2 (7)	1 (4)
+6	1 (3)	0
+7	3 (10)	0
	Mean (SD) levels change	
	2.6 (2.1)	1.6 (1.7)
Difference between activity groups in mean levels change from baseline to 4-week visit (95% CI)*	0.9 (−0.1, 2.0)	
***P* Value†**	0.07	
Distribution of visual acuity scores at 4-week visit	*n* (%)	
20/500	0	1 (4)
20/400	0	0
20/320	0	1 (4)
20/250	0	0
20/200	0	1 (4)
20/160	0	2 (7)
20/125	2 (7)	2 (7)
20/100	2 (7)	2 (7)
20/80	3 (10)	1 (4)
20/63	10 (33)	4 (14)
20/50	2 (7)	3 (11)
20/40	4 (13)	3 (11)
20/32	4 (13)	6 (21)
20/25	0	1 (4)
20/20	3 (10)	1 (4)
	Mean (SD) logMAR	
	0.42 (0.22)	0.51 (0.35)

*A positive difference indicates that the mean lines change from baseline to the 4-week visit was greater in the near activities group than the non-near activity group.

†*P* value for difference in means between activity groups from *t* test.

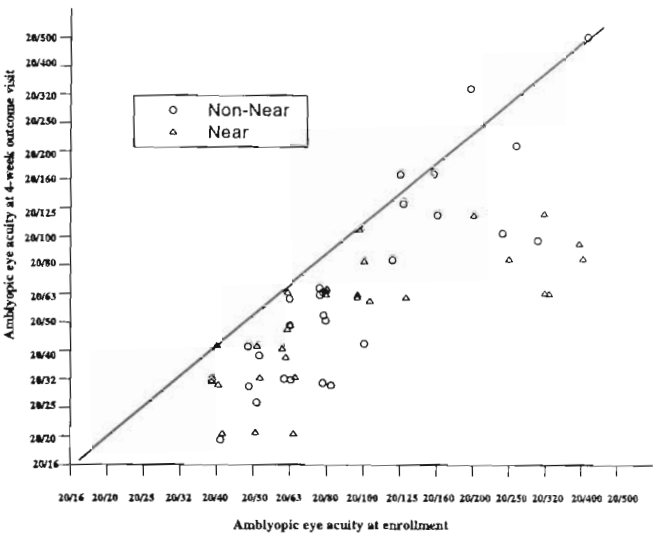

FIG 2. Comparison of amblyopic eye enrollment acuity and 4-week outcome acuity. Scatter plot of enrollment versus 4-week outcome acuity for N = 58 patients with a 4-week outcome acuity. Line corresponds to the unity line. Patients below the line showed an improvement in visual acuity.

view, or that the parent wished to please the telephone interviewer. One advantage of the weekly telephone interview was the opportunity to (1) remind the parent of the treatment group assignment and (2) remind the parent to complete the calendar and to mail the calendar to the coordinating center. The combination of daily calendars and weekly telephone interviews appears to be a good method of collecting data on actual activities performed while patching. We did not specifically assess the value of the phone calls as a potential compliance aid in patching therapy. We speculate that weekly phone calls may be of value in *efficacy* studies of amblyopia treatment, to answer purer scientific questions, but weekly phone calls would not be desirable in real-world *effectiveness* studies, since weekly phone calls are unlikely to be feasible in routine care.

Although our study was purposely not designed with sufficient statistical power to address improvement in the amblyopic eye, we did find a greater improvement in amblyopic eye visual acuity in the near activities group than the non-near group, on average about one logMAR line of visual acuity. However, this result did not reach statistical significance (P = 0.07) and therefore a definitive conclusion cannot be made. In addition, the enhancement of patching effect with near activities was only seen in our patients with severe amblyopia, although here our numbers are small. The effect of near versus non-near activities while patched should now be addressed in an appropriately powered randomized trial, of appropriate duration, with sufficient sample size to address possible effect modification by severity of amblyopia.

We have previously studied 2 hours of patching per day combined with near visual activities in moderate amblyopia.[1] Given the success of 2 hours of daily patching in many children with amblyopic eye acuity of 20/40 to 20/80, we have questioned[1] whether 2 hours per day might be sufficient in children with worse amblyopic eye acuity. At the 4-week visit in our present study, the 13 patients with severe amblyopia in the near group improved by a mean of 3.7 ± 2.5 logMAR levels. This compares to an improvement of 3.5 logMAR levels at the 5-week visit in the 6-hour daily patching group of our previous randomized trial in severe amblyopia.[2] These preliminary data suggest that some children with severe amblyopia might respond to 2 hours of daily patching and such a regime for severe amblyopia is worthy of future study.

We could identify no sources of bias or confounding to explain our primary finding that families instructed to perform near activities did perform near activities far more than families instructed to perform non-near activities. There may be some disagreement among eye-care providers regarding whether a specific activity, for example, eating, was a near or non-near activity. Nevertheless, we found excellent overall separation of activities between our two groups, suggesting that a future randomized treatment trial is feasible. The extent of calendar completion and phone interview completion was similar in both groups. Whether a child was assigned near activities or non-near activities did not appear to influence the amount of patching time completed. Both groups were instructed to perform 2 hours of daily patching and both groups reported performing similar amounts of patching. Visual acuity was measured using a standardized protocol,[8] with a high level of automation,[9] and although the testers were not masked in the present study, we believe it is highly unlikely that they could systematically influence the results over multiple sites.

In conclusion, if children receiving treatment for amblyopia were instructed to perform near activities while patching, they actually spent more time performing those near activities than children who were instructed to perform non-near activities. This finding allows us to design a future randomized trial to study the effect of patching with near activities on amblyopic eye visual acuity compared with patching without near activities.

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Clinical Sites That Participated in This Protocol. Sites are listed in order by number of patients enrolled into the study. The number of patients enrolled is noted in parenthesis preceded by the site location and the site name. Personnel are listed as (I) for Investigator, (C) for Coordinator, and (V) for Visual Acuity Tester.

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Lancaster, PA - Family Eye Group (12). David I. Silbert (I); Don D. Blackburn (I); Eric L. Singman (I); Noelle S. Matta (C); Shannon M. Butler (V); Suanne E. Carner (V); Cristina M. Corradino (V); Troy J. Hosey (V); Diane M. Jostes (V); Alyson B. Keene (V); Melissa A. Kelly (V); Stephanie R. Kilgore (V); Michelle M. Lindsey (V); Scarlett T. Musser (V); Tonji L. Nelson (V); Danae L. Nelson (V); Tiana M. Ober (V); Wendy L. Piper (V); Sara L. Weit (V); Sylvia R. Wright (V).

Anchorage, AK - Ophthalmic Associates (5). Robert W. Arnold (I); Mary Diane Armitage (C); Nancy H. Brusseau (V); Maru versus Gindling (V); Karen M. Lowe (V).

Dallas, TX - Pediatric Ophthalmology, PA (4). David R. Stager, Sr. (I); Priscilla M. Berry (I); David R. Stager, Jr. (I); Joost Felius (C); Sarah E. Morale (V).

Indianapolis, IN - Indiana University School of Optometry (4). Don W. Lyon (I); Michelle L. Varvel (C); John P. Downey (V); Christy C. Hohenbary (V); Brad M. Sutton (V).

Miami, FL - Bascom Palmer Eye Institute (4). Susanna M. Tamkins (I); Eva M. Olivares (C); Nihusa P. Oviedo (C); Bruce D. Bailey (V); Mirna Garcia (V).

Boise, ID - Katherine Ann Lee, MD, PA (3). Katherine A. Lee (I); Bonita R. Schweinler (C).

Memphis, TN - Southern College of Optometry (3). Erin R. Nosel (I); Kristin K. Anderson (I); Lindsay C. Moran (C); Subba Rao Gollamundi (I); Tom R. Karkkainen (V); Christopher W. Lievens (V); Bernard I. Sparks (V).

South Charleston, WV - Children's Eye Care and Adult Strabismus Surgery (3). Deborah L. Klimek (I).

Baltimore, MD - Wilmer Institute (2). Michael X. Repka (I); Carole R. Goodman (C); Xiaonong Liu (C).

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An Eye on the Arts – The Arts on the Eye

Let me say that, from then on, I began to think of her so deeply with my whole shameful heart that my many sighs were proof of it, for all of them on issuing forth would repeat what my heart was saying, that is, the name of that most gracious one and how she departed from us. And many times it happened that some thoughts were so filled with anguish that I would forget what I was thinking and where I was. By this rekindling of sighs, the tears which had subsided began to flow again, so that my eyes seemed to be two objects whose only desire was to weep. And often it occurred that after continuous weeping a purplish color encircled my eyes, as often appears in one who has endured affliction. In this way they were justly rewarded for their inconstancy, and from then on they could not look at any person who might look back at them in such a way as to encourage again a similar inclination. And in order for it to be known that such an evil desire and foolish temptation had been destroyed, so that the poetry I had written before would raise no question, I decided to write a sonnet which should contain the essence of what I have just related. And I wrote: *Alas! By the full force,* and I said "Alas!" because I was ashamed of the fact that my eyes had been so faithless.

I do not divide this sonnet because its reason for existence makes it clear enough.

Alas! By the full force of countless signs
born of the thoughts that overflow my heart,
the eyes are vanquished, and they do not dare
to return the glance of anyone who sees them.
They have become twin symbols of my yearning,
to show, by shedding tears, how much I suffer;
and many times they mourn so much that Love
encircles them with martyrdom's red crown.
—Dante Alighieri (from *Vita Nuova*)