Published in final edited form as:

Arch Ophthalmol. 2008 December ; 126(12): 1634–1642. doi:10.1001/archophthalmol.2008.107.

Patching vs Atropine to Treat Amblyopia in Children Aged 7 to 12 Years: A Randomized Trial

Pediatric Eye Disease Investigator Group*

* The writing committee and a list of the members of the Pediatric Eye Disease Investigator Group (PEDIG) participating in the study appear in the acknowledgements.

Abstract

Objective—To compare patching with atropine eye drops in the treatment of moderate amblyopia (20/40–20/100) in children age 7 to 12 years.

Methods—In a randomized multi-center clinical trial, 193 children with amblyopia were randomized to weekend atropine or patching 2 hours per day of the sound eye.

Main Outcome Measure—Masked assessment of amblyopic eye visual acuity using the EETDRS testing protocol at 17 weeks.

Results—At 17 weeks, visual acuity had improved from baseline by an average of 7.6 letters in the atropine group and 8.6 letters in the patching group. The mean difference (patching minus atropine) between groups adjusted for baseline acuity was 1.2 letters (ends of complementary 1-sided 95% confidence intervals for noninferiority = -0.7 and +3.1 letters). Based on the confidence intervals this difference met the pre-specified definition for equivalence (ends of confidence intervals <5 letters). Amblyopic eye visual acuity was 20/25 or better in 15 subjects (17%) in the atropine group and 20 subjects (24%) in the patching group (difference = 7%, 95% confidence interval = -3% to 17%).

Conclusions—Treatment with atropine or patching leads to similar degrees of improvement in 7 to 12 year old children with moderate amblyopia. About 1 in 5 achieves 20/25 or better visual acuity in the amblyopic eye.

Application to Clinical Practice—Treatment of older children with unilateral amblyopia.

Introduction

To explore the effectiveness of amblyopia treatment in children 7 years and older, the Pediatric Eye Disease Investigator Group (PEDIG) previously conducted a randomized trial of 507 subjects aged 7 to 17 years with amblyopic eye visual acuity ranging from 20/40 to 20/400.¹ In the 7 to 12 year olds (N=404), 53% of the optical correction plus patching and atropine group subjects had improvement in amblyopic eye acuity of 10 or more letters compared with 25% of the optical correction only group (P<0.001), demonstrating the effectiveness of amblyopia treatment in this age range.

The previous study was one of the first randomized clinical trials of treatment in older children with amblyopia. Therefore, that study was designed to combine patching and atropine for 7 to 12 year olds, to maximize the chance of finding a treatment effect, if such an effect existed. Once treatment of older children had been found to have merit, most clinicians did not initiate amblyopia treatment by combining patching and atropine. We therefore designed the present

randomized clinical trial to compare these two therapies in 7 to 12 year olds with amblyopia caused by anisometropia and/or strabismus.

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 (PEDIG) at 39 clinical sites. The protocol and Health Insurance Portability and Accountability Act (HIPAA) compliant informed consent forms were approved by institutional review boards, and a parent or guardian (referred to subsequently as “parent”) of each study subject gave written informed consent and the subject gave assent as required. Study oversight was provided by an independent data and safety monitoring committee. The study is listed on www.clinicaltrials.gov, under identifier NCT00315328. The protocol, which is available on the PEDIG website (www.pedig.net), is summarized below.

Synopsis of Study Design

Baseline testing included (1) measurement of visual acuity in each eye using the Electronic Early Treatment Diabetic Retinopathy Study (E-ETDRS) visual acuity testing protocol, administered by a study-certified vision examiner,² (2) an ocular examination, (3) a cycloplegic refraction, (4) measurement of ocular alignment with a simultaneous prism and cover test (SPCT) at distance and near, and (5) assessment of binocularity with the Randot Preschool Stereoacuity Test (Stereo Optical Co., Chicago, IL).

The major eligibility criteria for the trial included (1) age 7.0 to <13.0 years, (2) visual acuity in the amblyopic eye between 48 and 71 letters (20/40 to 20/100 inclusive), (3) visual acuity in the sound eye of 79 letters or better (20/25 or better), (4) intereye acuity difference of ≥ 15 letters (3 lines), (5) the presence of or a history of an amblyogenic factor meeting study-specified criteria for strabismus and/or anisometropia, and (6) the wearing of optimal spectacle correction for a minimum of 16 weeks or until stability of visual acuity was documented (no improvement in amblyopic eye visual acuity at 2 consecutive visits at least 4 weeks apart). Exclusion criteria included (1) myopia greater than -0.25 diopters (D) spherical equivalent in either eye, (2) treatment for amblyopia (other than spectacle correction) within the 6 months prior to enrollment, and (3) Down Syndrome. Table 1 (journal website) provides a complete listing of the eligibility and exclusion criteria.

Data entered on the PEDIG website were used to randomly assign each subject (using a permuted blocks design stratified by site and amblyopic eye visual acuity) with equal probability to one of two treatment groups: atropine 1% each weekend day in the sound eye or patching 2 hours per day of the sound eye.

Follow-up visits were performed at 5 weeks (± 1 week) and 17 weeks (± 1 week), the latter being the primary outcome visit. At each visit, visual acuity was measured in each eye using the E-ETDRS testing procedure. Measurement of visual acuity using the ETDRS procedure is reported as a letter score, with a score of 85 approximating 20/20 and each 5 letters approximating one line of acuity.³ At the 17-week visit, the examiner was masked to treatment group. To accomplish masking the sound eye was patched for patients in both groups before the masked examiner saw the patient. Ocular alignment was assessed and stereoacuity was measured at the 17-week visit. For subjects using atropine, the 17-week visit outcome examination testing was split into two visits with amblyopic eye acuity tested at the first visit and sound eye acuity, ocular alignment, and stereoacuity assessed at a second visit after atropine had been discontinued for two weeks.

Visual acuity in each eye was tested a second time at the 17-week visit, with the better of the two acuity measurements used to determine whether the subject continued in the study. Subjects were discontinued from the study if either (1) amblyopia had resolved (amblyopic eye acuity either ≥ 84 letters or no more than 3 letters worse than the sound eye), (2) visual acuity in the amblyopic eye had not improved at least 5 letters (1 line) from baseline and at least 3 letters from the 5-week visit, (3) alternate amblyopia treatment had been received (e.g., patching for the atropine group or atropine for the patching group) or (4) reverse amblyopia occurred. Subjects in whom amblyopia had improved but not resolved remained on their randomization-assigned treatment and were followed every 8 weeks (± 1 week) until either (1) amblyopic eye acuity was ≥ 84 letters (20/20) or no more than 3 letters worse than sound eye acuity or (2) there was no further improvement in the amblyopic eye acuity (acuity no more than 2 letters better than that at the prior visit on 2 tests of acuity at the same visit).

Treatment Protocols

For the patching group, adhesive skin patches, provided by the study (Coverlet Eye Occlusors, Beiersdorf-Jobst, Inc., Rutherford College, NC), were used unless there was a skin allergy or irritation unresponsive to both local treatment with a skin emollient and a change in brand of patch in which case a spectacle occluder could be used. At the 5-week visit, if the amblyopic eye acuity had not improved by at least 5 letters from baseline, treatment was increased to 4 hours of daily patching. If amblyopic eye acuity had reached 79 letters or better by the 5-week visit, the patching regimen was continued or tapered, but a minimum of one hour of daily patching was required until the 17-week outcome exam was completed.

For the atropine group, atropine ophthalmic solution 1% was provided. Sunglasses were provided, which were to be worn with a brimmed hat when the child was in sunlight. A reading test was performed with cycloplegia of the sound eye. If the subject was unable to read grade-appropriate print, the study paid for reading glasses to be used during school and for homework. If an allergy to atropine developed, homatropine ophthalmic solution 5% was substituted. At the 5-week visit, if the amblyopic eye acuity had not improved by at least 5 letters from baseline, atropine was increased to 1 drop in the sound eye daily. Prior to the 17-week outcome exam, atropine was not discontinued unless an adverse effect of treatment occurred.

Treatment-group specific instruction sheets were given to the parent, which listed examples of “near” activities to be performed during treatment (patching subjects were to perform near activities for one hour while wearing the patch; atropine subjects were to perform near activities for one hour any time of the day). Near activities included tasks that specifically required up-close eye-hand coordination such as crafts, reading, writing, and computer or video games.

At each visit, the parent was queried about side effects of treatment and the visual acuity of the sound eye was measured. At the 17-week visit, if acuity in the sound eye was worse than 84 letters and reduced from baseline by 5 letters (1 line) or more, then a cycloplegic refraction was performed and visual acuity was tested again. If acuity was still reduced and there was a change in refraction from the current spectacles, new lenses were prescribed. Regardless of whether a change in correction was made, the patient remained off treatment and returned for a recheck of acuity in 1 to 4 weeks.

Adherence to the treatment protocol was assessed by having the parent record on a calendar the treatment received each day. Based on discussion with the parent and review of the calendars brought in at each visit, the investigator made an assessment of compliance as excellent (76%-100% of prescribed treatment completed), good (51%-75%), fair (26%-50%), or poor ($\leq 25\%$).

Parents additionally completed the Amblyopia Treatment Index (ATI)⁴ questionnaire at the 5-week and the 17-week visits. The questionnaire consisted of 18 Likert-type items with five response choices ranging from "strongly agree" to "strongly disagree", and was designed to measure the impact of the treatment on the child and the family, with subscales measuring social stigma, compliance and adverse effects for each treatment arm. A copy of the full questionnaire is available online (www.pedig.net).

Statistical Methods

The trial was designed to evaluate whether patching and atropine are equivalent treatments for amblyopia in children 7 to 12 years of age. The sample size was computed to be 180 subjects to have 90% power and a type 1 error of 5% for an equivalence limit of 5 letters (1 line) based on the following assumptions derived from prior PEDIG studies:^{1, 5} standard deviation of 17-week visual acuity scores of 10 letters, correlation between outcome and baseline visual acuity scores of 0.30, and 10% loss to follow up.

The primary outcome was the masked 17-week amblyopic eye visual acuity score. The treatment groups were compared in an analysis of covariance model in which the acuity scores were adjusted for baseline acuity. Treatment equivalence was to be declared if the ends of the two 1-sided 95% confidence intervals constructed on the difference between adjusted mean visual acuity scores for the two groups were completely contained within the designated equivalence interval of ± 5 letters. To be included in the primary analysis, the 17-week outcome examination could be performed no earlier than 13 weeks following randomization and no later than 26 weeks to accommodate visits that were not completed within the protocol-specified time window of 16 to 18 weeks. Similar results were also obtained from the following alternative analyses (data not shown): (1) including only visits completed in the visit window of 17 ± 1 week from randomization, (2) using the last-observation-carried-forward method to impute for missing data, and (3) including baseline variables imbalanced between groups in the ANCOVA model.

As secondary analyses, the proportions of patients in each treatment group with amblyopic eye visual acuity at 17 weeks of $\geq 20/25$ (≥ 78 letters) and the proportions improving 15 or more letters from baseline were compared by constructing 2 one-sided 95% confidence intervals on the difference in proportions.

Methods used to analyze the amblyopic eye acuity scores at the 5-week visit, and the maximum visual acuity at the 17-week outcome visit or subsequent visits paralleled the analysis conducted on the 17-week outcome visit data.

A treatment group difference in sound eye visual acuity at 17-weeks was evaluated in an analysis-of-covariance model in which the sound eye acuities were adjusted for baseline acuity. Wilcoxon rank sum tests were used to assess treatment group differences in 1) the parent questionnaire subscale scores at 5 weeks and at 17 weeks and 2) change in Randot Preschool stereoacuity levels (from baseline to the 17-week outcome examination). Within each treatment group, the difference between baseline and 17-week Randot Preschool stereoacuity levels was evaluated with a Wilcoxon sign-rank test.

All analyses followed the intention-to-treat principle (i.e., the treatment group data were based on the randomization assignments, not on the actual treatment received or whether the treatment protocol was followed). All results are reported in letters of visual acuity (5 letters is approximately equivalent to one logMAR line of visual acuity).

Results

Baseline Characteristics

Between August 2005 and July 2007, 193 subjects were enrolled by 39 certified sites (with 95 assigned to the atropine group and 98 to the patching group). The average age of the subjects was 9.0 years; 53% were female. Sixty-four percent of subjects were white, 22% were Hispanic or Latino, 10% were African-American, and 4% reported other race/ethnicity. The mean letter score in the amblyopic eyes at enrollment was 62.1 letters (approximately 20/63), with a mean inter-ocular difference in visual acuity between the amblyopic and fellow eyes of 23.8 letters (approximately 5 lines). Table 2 provides the baseline characteristics for each treatment group.

Follow Up

The 17-week primary outcome examination was completed by 88 of 95 (93%) subjects in the atropine group and 84 of 98 (86%) subjects in the patching group (Figure 1). The vision tester was masked to treatment group for 97% of these examinations (97% in the atropine group and 98% in the patching group).

Treatment

Four subjects received treatment that deviated from the study protocol: at the 5-week visit, 2 subjects randomized to the atropine group were prescribed daily patching and 2 subjects randomized to the patching group were prescribed weekend atropine. Among the remaining 87 subjects in the atropine group who completed at least one follow-up exam, 51 (59%) used only weekend atropine, 32 (37%) were increased per protocol to daily atropine at 5 weeks, 2 (2%) were switched from atropine to homatropine, and 2 (2%) were increased to daily atropine against protocol at 5 weeks. Among the remaining 89 subjects in the patching group who completed at least one follow-up exam, 57 (64%) were treated with 2 hours of patching throughout the study while 31 (35%) had patching increased per protocol to 4 hours per day at the 5-week visit.

Patient adherence with the prescribed treatment over follow up in the atropine group was judged by the investigator to be excellent in 59%, good in 25%, fair in 15%, and poor in 1% of subjects and in the patching group to be excellent in 50%, good in 30%, fair in 18%, and poor in 2% of subjects.

Amblyopic Eye Visual Acuity

At the 5-week visit, visual acuity had improved from baseline by an average of 6.2 letters in the atropine group and by 6.8 letters in the patching group. At the 17-week primary masked outcome exam, visual acuity had improved from baseline by an average of 7.6 letters in the atropine group and 8.6 letters in the patching group (Table 3). The mean difference (patching minus atropine) between groups adjusted for baseline acuity was 1.2 letters (ends of complementary 1-sided 95% confidence intervals for noninferiority = -0.7 and +3.1 letters). Based on the confidence intervals this difference met the pre-specified definition for equivalence (ends of confidence intervals <5 letters). Amblyopic eye visual acuity was 20/25 or better in 15 subjects (17%) in the atropine group and 20 subjects (24%) in the patching group (difference = 7%, 95% confidence interval = -3% to 17%), Figure 2. Fifteen subjects (17%) in the atropine group and 21 subjects (25%) in the patching group improved fifteen or more letters from baseline (difference = 8%, 95% confidence interval = -2% to 18%).

Post 17-week Follow-up

Thirty-three subjects in the atropine group and 33 in the patching group whose best tested visual acuity at the 17-week exam was improved from baseline continued on treatment. Follow up

continued for one 8-week cycle in 29 subjects in the atropine group and 27 subjects in the patching group, and two 8-week cycles in 4 and 6 subjects, respectively. In the atropine group, 4 subjects had additional improvement of 5-9 letters, one 10-14 letters, and one 15 or more letters. In the patching group, 6 subjects improved 5-9 letters and one 15 or more letters. Overall, the mean improvement between visual acuity at the 17-week outcome and subsequent follow-up visits was less than one letter in both groups, respectively. Maximum visual acuity measured at the 17-week outcome or subsequent follow-up visits was 20/25 or better in 18 subjects (20%) in the atropine group and 22 subjects (26%) in the patching group (difference = 6%, 95% confidence interval = -5% to 16%). Sixteen subjects (18%) in the atropine group and 24 subjects (29%) in the patching group improved 15 or more letters from baseline (difference = 10%, 95% confidence interval = 0% to 21%).

The visual acuity results were not altered by adjusting for the imbalance between groups in race, cause of amblyopia, and refractive error in the amblyopic and sound eyes (data not shown). Results in subgroups based on age, baseline acuity, prior treatment for amblyopia, and cause of amblyopia appeared similar to the overall results (Table 4 journal website).

Stereoacuity

Stereoacuity improved from baseline to 17-weeks in both the atropine and patching groups ($P=0.96$, Table 5). Randot Preschool Stereoacuity was measured in seven distinct levels of arc sec: >800, 800, 400, 200, 100, 60 and 40 arc sec. Among subjects in the atropine group, at 17-weeks the Randot Preschool score was within one level of baseline in 54 (67%) of subjects, two or more levels better in 18 (22%), and two or more levels worse in 9 (11%) ($P=0.04$). Among subjects in the patching group, at 17-weeks the Randot Preschool score was within one level of baseline in 57 (73%) of subjects, two or more levels better in 17 (22%), and two or more levels worse in 4 (5%) ($P=0.003$).

Amblyopia Treatment Index

The Parental Amblyopia Treatment Index was completed by 77 of 95 (81%) in the atropine group and by 75 of 98 (77%) of the parents in the patching group at the 5-week visit and by 64 of 95 (67%) and 66 of 98 (67%), respectively, at the 17-week visit. The questionnaire scores were similar for the atropine and patching groups on the *adverse effects* subscale (mean = 2.32 versus 2.27 at five weeks, $P=0.72$ and mean = 2.22 versus 2.28 at 17-weeks, $P=0.70$), but slightly favored the atropine group on the *social stigma treatment* subscale (mean = 1.91 versus 2.21 at five weeks, $P=0.03$, and mean = 1.91 versus 2.37 at 17 weeks, $P<0.001$) and the *compliance* subscale (mean = 2.03 versus 2.46 at five weeks, $P=0.001$, and mean = 2.03 versus 2.59 at 17-weeks, $P<0.001$).

Adverse Effects

At 17-weeks, mean change in sound eye visual acuity from baseline was 0.3 ± 0.7 letters in the atropine group and 1.5 ± 0.7 letters in the patching group (mean difference between groups adjusted for baseline = 1.3 letters, 95% confidence interval, 0.4 to 2.2 letters, Table 6). There were no subjects diagnosed with reverse amblyopia. During the study, there were no differences between treatment groups in the number of subjects who developed new-onset strabismus or had an increase or decrease in a pre-existing strabismus (Table 7 journal website).

In the atropine group, ocular side effects, most commonly light sensitivity, were reported by 14 (14%) subjects. Systemic side effects were reported by 3 subjects (1 reported tachycardia, 1 reported dry mouth, and 1 reported irritability and headache). In the patching group, 4 subjects had moderate to severe irritation from patching. No cases of persistent constant diplopia were reported.

Discussion

In this study of 193 7 to 12 year olds with moderate amblyopia, treatment with patching or atropine produced similar degrees of improvement in visual acuity of the amblyopic eye, with about 40% of subjects having a 2 or more line improvement in visual acuity. The response to treatment was seen irrespective of severity of amblyopia (within the 20/40 to 20/100 range studied), cause of amblyopia, and whether the amblyopia had been previously treated. About one in five subjects had additional improvement beyond 17 weeks, and most subjects still had residual amblyopia at the end of the study.

Due to differences in study design, we cannot compare the results of combined therapy (atropine plus patching) in our previous study of older children to the results of monotherapy (atropine or patching) in the current study. A main difference in design was the requirement in the current study that subjects had to be treated with spectacles alone until the visual acuity showed no further improvement prior to entering the study; whereas in the prior study, spectacle correction was provided at the time of study entry. Such previous spectacle treatment would be expected to reduce the subsequent improvement when treating with either patching or atropine. A second difference between the studies was differing durations of follow-up, which may have biased the previous study toward finding less treatment effect, because if there was no improvement by the first 6-week visit, the patient was classified as a non-responder and the study ended for that patient. A formal comparison of combined versus monotherapy would require another randomized clinical trial.

Both treatments were well tolerated. There has been concern about a potential adverse effect of atropine-induced blur on stereoacuity development. However, stereoacuity improved on average a similar amount in both treatment groups. Two additional potential adverse effects associated with amblyopia therapy, reverse amblyopia and intractable constant diplopia, did not occur in this study population. Although there was a statistically significant difference between treatment groups in change from baseline in sound eye visual acuity, the difference (about one letter on average) was clinically insignificant. In our previous study of 507 older children (7 to <18 years old) we also found no significant adverse effects of patching and atropine.¹

When prescribing atropine for older children with amblyopia, a concern is that the cycloplegia will impair a child's ability to effectively perform school work. We tested the subject's ability to see grade-appropriate print after cycloplegia of the sound eye. Only 12% (11/95) of the children had difficulty seeing grade-appropriate sized print and were prescribed reading glasses (by protocol).

While the treatment response was equivalent for patching and atropine the quality of life assessment made with the Amblyopia Treatment Index favored atropine with respect to compliance and social stigma. This finding should be viewed with caution due to the lower than optimal questionnaire completion rate. The low completion rate primarily was due to the parent or guardian responsible for treating the child not being at the visit. However, the current study results favoring the atropine group with respect to compliance and social stigma were similar to those found in our previous study comparing atropine with patching in younger children.⁶

We could identify no sources of confounding or bias to explain our findings. The visual acuity results were not altered by adjusting for imbalances between groups in race, cause of amblyopia, and refractive error in the amblyopic and sound eyes. The follow-up visit rate was slightly higher in the atropine group than in the patching group (93% vs. 86%) but an analysis accounting for incomplete follow up gave similar results. Although the subjects and investigators were by the nature of this study unmasked to the treatment group assignments,

the outcome was based on a visual acuity test administered by an individual masked to the treatment assignment. In addition, the computerized method of visual acuity testing used in the trial minimized the possibility that knowledge of treatment group will bias the results.²

In translating the results of this study into clinical practice, the findings from this report combined with our previous study¹ indicate that treatment with patching or atropine in combination or alone can improve amblyopia in children 7 to 12 years of age. The degree of response varies, and in most cases, the amblyopic eye does not achieve the visual acuity level of the sound eye. Based on the results of the prior PEDIG study of this age group in which subjects were observed for one year after treatment was discontinued, it is likely that most patients treated for amblyopia in this age range will retain the visual acuity level achieved after treatment is discontinued.⁷

Acknowledgments

This study was supported by the National Eye Institute of the National Institutes of Health, Department of Health and Human Services EY011751 (PEDIG).

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*Center received support utilized for this project from an unrestricted grant from Research to Prevent Blindness Inc., New York, New York.

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*Amblyopic eye visual acuity is < 3 letters better than at the previous visit

†Resolved defined as amblyopic eye visual acuity $\geq 20/20$ or IOD ≤ 3 letters

Figure 1.

Flow chart showing study completion in each treatment group.

Figure 2.
Cumulative distribution of amblyopic eye visual acuity scores at 17-week outcome exam according to treatment group.

Table 1

(Journal Website): Eligibility and Exclusion Criteria

Eligibility Criteria

1. Age 7 to 12 years
2. Amblyopia associated with strabismus (comitant or incomitant), anisometropia, or both, meeting the following criteria:
 - ◆ Strabismic amblyopia: At least one of the following criteria must be met and criteria are not met for combined-mechanism amblyopia:
 - *Heterotropia at distance and/or near fixation on examination (with or without spectacles)*
 - *History of strabismus surgery (or botulinum)*
 - *Documented history of strabismus which is no longer present (and which, in the judgment of the investigator, is the cause of amblyopia)*
 - ◆ Anisometropic amblyopia: At least one of the following criteria must be met:
 - *≥ 0.50 D difference between eyes in spherical equivalent*
 - *≥ 1.50 D difference between eyes in astigmatism in any meridian*
 - ◆ Combined mechanism amblyopia: Both of the following criteria must be met:
 - *Criteria for strabismus are met (see above)*
 - *≥ 1.00 D difference between eyes in spherical equivalent or ≥ 1.50 D difference between eyes in astigmatism in any meridian*
3. Visual acuity, measured using the E-ETDRS visual acuity testing protocol meeting the following criteria:
 - ◆ Best corrected visual acuity in the amblyopic eye 19 to 71 letters inclusive (20/40 to 20/400 inclusive)
 - ◆ Best corrected visual acuity in the sound eye ≥ 79 letters (20/40 or better)
 - ◆ Inter-eye acuity difference ≥ 15 letters (i.e., amblyopic eye acuity at least 3 lines worse than sound eye acuity)
4. No amblyopia treatment other than spectacles used within six months prior to enrollment. Any treatment more than 6 months prior to enrollment is acceptable
5. Spectacle correction for measurement of enrollment visual acuity must meet the following criteria and be based on a cycloplegic refraction that is no more than 6 months old.
 - For subjects meeting criteria for strabismus (see above)
 - *Hypermetropia if corrected must not be undercorrected by more than +1.50 D spherical equivalent, and the reduction in plus sphere must be symmetric in the two eyes. Otherwise, spectacle correction is at investigator discretion.*
 - For subjects meeting criteria for anisometropia or combined-mechanism (see above)
 - *Spherical equivalent must be within 0.50 D of fully correcting the anisometropia*
 - *Hypermetropia must not be undercorrected by more than +1.50 D spherical equivalent, and reduction in plus must be symmetric in the two eyes*
 - *Cylinder power in both eyes must be within 0.50 D of fully correcting the astigmatism*
 - *Cylinder axis in the spectacle lenses in both eyes must be within 6 degrees of the axis of the cycloplegic refraction when cylinder power is ≥ 1.00 D*
- ◆ Spectacles meeting above criteria must be worn either:
 - for 16 weeks immediately prior to enrollment, or
 - until visual acuity in amblyopic eye is stable (defined as two consecutive visual acuity measurements by the same testing method at least 4 weeks apart with no improvement of one logMAR line or more)

- *An acuity measurement done any of the following ways may be considered the first of two consecutive measurements: 1) in current glasses , 2) in trial frames with full correction of hypermetropia with cycloplegia, or 3) by having the patient return in new glasses for first measurement. Note: since this determination is a pre-study procedure, the method of measuring visual acuity is not mandated.*

Exclusion Criteria

1. Presence of an ocular cause for reduced vision
 2. Myopia $\geq$ -0.25 D spherical equivalent in either eye
 3. Prior intraocular or refractive surgery
 4. Known allergy to atropine or other cycloplegic drugs
 5. Known skin allergy to patch or bandage adhesives
 6. Current vision therapy or orthoptics
 7. Down Syndrome
-

Table 2

Baseline Characteristics According to Treatment Group

	Atropine N=95 n (%)[*]	Patching N=98 n (%)[*]
Gender: Female	54 (57)	48 (49)
Race / Ethnicity		
White	56 (59)	68 (69)
African-American	11 (11)	8 (8)
Hispanic or Latino	23 (24)	20 (20)
Asian	1 (1)	0
More than one race	2 (2)	1 (1)
Not reported	2 (2)	1 (1)
Age at Enrollment		
7 to <8 years	28 (29)	35 (36)
8 to <9 years	26 (27)	24 (24)
9 to <10 years	16 (17)	17 (17)
10 to <11 years	10 (11)	8 (8)
11 to <12 years	7 (7)	8 (8)
12 to 12 years	8 (8)	6 (6)
Mean (SD)	9.1 (1.6)	8.9 (1.5)
Prior Treatment for Amblyopia at Enrollment		
None	68 (72)	71 (72)
Patching	16 (17)	16 (16)
Atropine	0	2 (2)
Patching and Atropine	11 (12)	9 (9)
Cause of Amblyopia		
Strabismus	33 (35)	28 (29)
Anisometropia	31 (33)	46 (47)
Strabismus and anisometropia	31 (33)	24 (24)
Distance Visual Acuity in Amblyopic Eye		
48-52 Letters: 20/100	13 (14)	6 (6)
53-57 Letters: 20/80	13 (14)	15 (15)
58-62 Letters: 20/63	22 (23)	24 (24)
63-67 Letters: 20/50	28 (29)	33 (34)
68-72 Letters: 20/40	19 (20)	20 (20)
Mean (SD) Letter Score	61.7 (6.6)	62.4 (5.7)

	Atropine N=95 n (%) [*]	Patching N=98 n (%) [*]
Distance Visual Acuity in Sound Eye		
78-82 Letters: 20/25	20 (21)	17 (17)
83-87 Letters: 20/20	47 (49)	43 (44)
88-92 Letters: 20/16	26 (27)	36 (37)
93-97 Letters: 20/12	2 (2)	2 (2)
Mean (SD) Letter Score	85.7 (3.4)	86.0 (3.6)
Intereye Acuity Difference		
Mean (SD) Difference in Letter Scores	24.0 (7.0)	23.5 (6.8)
Refractive Error in Amblyopic Eye		
< 0 D	2 (2)	2 (2)
0 to <+1.00D	10 (11)	8 (8)
+1.00 to <+2.00D	6 (6)	13 (13)
+2.00 to <+3.00D	8 (8)	10 (10)
+3.00 to <+4.00D	16 (17)	23 (23)
≥+4.00D	53 (56)	42 (43)
Mean (SD) logMAR	+4.10 (2.19)	+3.57 (2.07)
Refractive Error in Sound Eye		
< 0 D	2 (2)	1 (1)
0 to <+1.00D	29 (31)	32 (33)
+1.00 to <+2.00D	17 (18)	33 (34)
+2.00 to <+3.00D	9 (9)	13 (13)
+3.00 to <+4.00D	6 (6)	7 (7)
≥+4.00D	32 (34)	12 (12)
Mean (SD) logMAR	+2.56 (2.22)	+1.84 (1.74)

D = diopters

SD = standard deviation

*
n (%) unless otherwise stated

Table 3

Amblyopic Eye Visual Acuity at the 5-week and 17-week Outcome Exam

	5-Week Exam		17-Week exam	
	Atropine N=89 n (%) [*]	Patching N=91 n (%) [*]	Atropine N=88 n (%) [*]	Patching N=84 n (%) [*]
Change in Letter Score from Baseline				
≥15 letters worse	0	0	0	1 (1)
10 to 14 letters worse	0	0	2 (2)	0
5 to 9 letters worse	6 (7)	3 (3)	3 (3)	0
± 4 letters	30 (34)	35 (38)	22 (25)	23 (27)
5 to 9 letters better	28 (31)	23 (25)	26 (30)	22 (26)
10 to 14 letters better	15 (17)	23 (25)	20 (23)	17 (20)
≥15 letters better	10 (11)	7 (8)	15 (17)	21 (25)
Mean (SD) change in letter score	6.2 (6.7)	6.8 (6.4)	7.6 (7.5)	8.6 (7.8)
Distribution of Visual Acuity				
23-27 letters: 20/320	0	0	0	0
28-32 letters: 20/250	0	0	0	0
33-37 letters: 20/200	0	0	0	0
38-42 letters: 20/160	0	0	0	1 (1)
43-47 letters: 20/125	0	0	1 (1)	0
48-52 letters: 20/100	4 (4)	3 (3)	4 (5)	3 (4)
53-57 letters: 20/80	7 (8)	6 (7)	6 (7)	3 (4)
58-62 letters: 20/63	14 (16)	11 (12)	12 (14)	5 (6)
63-67 letters: 20/50	14 (16)	19 (21)	14 (16)	13 (15)
68-72 letters: 20/40	24 (27)	13 (14)	15 (17)	20 (24)
73-77 letters: 20/32	16 (18)	27 (30)	21 (24)	19 (23)
78-82 letters: 20/25	6 (7)	7 (8)	10 (11)	14 (17)
83-87 letters: 20/20	3 (3)	5 (5)	4 (5)	6 (7)
88-92 letters: 20/16	1 (1)	0	1 (1)	0
Mean (SD) Letter Score	67.8 (8.7)	69.2 (8.2)	69.2 (9.2)	71.0 (8.9)
Snellen Equivalent	20/40 ⁻²	20/40 ⁻¹	20/40 ⁻¹	20/40 ⁺¹
20/25 or better (≥78 letters)	10 (11)	12 (13)	15 (17)	20 (24)
Mean interocular difference (letters)	15.6	17.0	13.2	14.4
Difference between treatment groups adjusted for baseline visual acuity (patching minus atropine)	0.7 letters		1.2 letters	
Ends of 1-sided 95% CI on difference	-0.9 letters 2.3 letters		-0.7 letters 3.1 letters	

	5-Week Exam		17-Week exam	
	Atropine	Patching	Atropine	Patching
	N=89	N=91	N=88	N=84
	n (%) [*]	n (%) [*]	n (%) [*]	n (%) [*]
between groups				

^{*}
n (%) unless otherwise stated

Table 4

(Journal Website): Visual Acuity in the Amblyopic Eye at 17-week Outcome Exam According to Baseline Patient Characteristics

Baseline Characteristic	N (Atropine, Patching)	Mean Baseline Visual Acuity (Atropine, Patching)	Mean Letters Improvement from Baseline to 17 weeks	
			Atropine	Patching
All Subjects	(88, 84)	(61.6, 62.4)	7.6	8.6
Age				
7 to <9 years	(50, 51)	(62.8, 62.7)	7.9	8.4
9 to <11 years	(25, 19)	(60.4, 62.8)	7.4	10.1
11 to 12 years	(13, 14)	(59.6, 60.8)	6.6	7.2
Baseline Amblyopic Eye Acuity				
≥ 20/50	(43, 45)	(67.0, 66.8)	7.1	7.4
< 20/50	(45, 39)	(56.6, 57.4)	8.0	10.0
Prior Amblyopia Treatment				
Yes	(25, 22)	(62.1, 62.3)	8.3	9.2
No	(63, 62)	(61.5, 62.5)	7.3	8.4
Cause of Amblyopia				
Strabismus	(31, 22)	(62.3, 63.7)	7.5	9.8
Anisometropia	(28, 42)	(62.1, 62.2)	7.9	10.0
Combined mechanism	(29, 20)	(60.5, 61.6)	7.2	4.3

Table 5

Randot Preschool Stereoacuity at Baseline and at the 17-week Outcome Exam by Treatment Group

All Subjects				
Randot Preschool Stereoacuity (arc second)	Baseline N (%)		17 Weeks N (%)	
	Atropine (N=88)	Patching (N=84)	Atropine (N=88)	Patching (N=84)
Failed pretest	4 (5)	5 (6)	4 (5)	1 (1)
>800	41 (47)	29 (35)	34 (39)	26 (31)
800	6 (7)	10 (12)	3 (3)	9 (11)
400	11 (13)	8 (10)	14 (16)	9 (11)
200	9 (10)	10 (12)	10 (11)	10 (12)
100	7 (8)	10 (12)	12 (14)	9 (11)
60	7 (8)	6 (7)	2 (2)	7 (8)
40	3 (3)	6 (7)	9 (10)	13 (15)
Subjects with Anisometropia* Only as Cause				
Randot Preschool Stereoacuity (arc second)	Baseline N (%)		17 Weeks N (%)	
	Atropine (N=28)	Patching (N=42)	Atropine (N=28)	Patching (N=42)
Failed pretest	1 (4)	2 (5)	0	0
>800	8 (29)	5 (12)	6 (21)	5 (12)
800	2 (7)	5 (12)	1 (4)	3 (7)
400	5 (18)	6 (14)	4 (14)	5 (12)
200	4 (14)	7 (17)	4 (14)	7 (17)
100	5 (18)	7 (17)	8 (29)	9 (21)
60	1 (4)	6 (14)	0	6 (14)
40	2 (7)	4 (10)	5 (18)	7 (17)
Subjects with Strabismus* Only or Combined Mechanism* Cause				
Randot Preschool Stereoacuity (arc second)	Baseline N (%)		17 Weeks N (%)	
	Atropine (N=60)	Patching (N=42)	Atropine (N=60)	Patching (N=42)
Failed pretest	3 (5)	3 (7)	4 (7)	1 (2)
>800	33 (55)	24 (57)	28 (47)	21 (50)
800	4 (7)	5 (12)	2 (3)	6 (14)
400	6 (10)	2 (5)	10 (17)	4 (10)
200	5 (8)	3 (7)	6 (10)	3 (7)
100	2 (3)	3 (7)	4 (7)	0
60	6 (10)	0	2 (3)	1 (2)
40	1 (2)	2 (5)	4 (7)	6 (14)

P= 0.96 from Wilcoxon Rank Sum Test for difference between treatment groups in distribution of levels of change from baseline to 17weeks

P= 0.78 from Wilcoxon Rank Sum Test for difference between treatment groups in distribution of levels of change from baseline to 17weeks

P= 0.99 from Wilcoxon Rank Sum Test for difference between treatment groups in distribution of levels of change from baseline to 17weeks

* Cause of amblyopia at time of randomization

* Cause of amblyopia at time of randomization

Table 6

Sound Eye Visual Acuity at the 17-week Outcome Exam

	17-Week Exam	
	Atropine N=88 n (%) [*]	Patching N=84 n (%) [*]
Change in Letter Score from baseline		
5 to 9 letters worse	7 (8)	4 (5)
± 4 letters	72 (82)	69 (82)
5 to 9 letters better	9 (10)	11 (13)
Mean (SD) change in letter score	0.3 (3.5)	1.5 (3.1)
Distribution of visual acuity		
73-77 letters: 20/32	4 (5)	2 (2)
78-82 letters: 20/25	12 (14)	5 (6)
83-87 letters: 20/20	42 (48)	31 (37)
88-92 letters: 20/16	29 (33)	42 (50)
93-97 letters: 20/12	1 (1)	4 (5)
Mean (SD) Letter Score	85.8 (3.9)	87.3 (3.8)
Snellen Equivalent	20/20	20/20 ⁺²

Among the 11 subjects with a 5 or more letter reduction in sound eye acuity, 7 subjects (4 in the atropine group and 3 in the patching group) tested 20/20 or better (≥ 83 letters) at 17 weeks. Of the remaining 4 subjects, 3 in the atropine group and 1 in the patching group tested 20/20 or better or within 5 letters of baseline with subsequent follow up off treatment.

*
n (%) unless otherwise stated

Table 7

(Journal Website): Ocular Alignment at Baseline and at the 17-week Outcome Exam by Treatment Group

Treatment Group = Atropine (N=89)			
Distance tropia at 17 weeks			
Distance tropia at baseline	0 PD n (%)	1-8 PD n (%)	>8 PD n (%)
0 PD	44 (98)	1 (2)	0
1-8 PD	7 (26)	19 (70)	1 (4)
>8 PD	0	6 (35)	11 (65)
Near tropia at 17 weeks			
Near tropia at baseline	0 PD n (%)	1-8 PD n (%)	>8 PD n (%)
0 PD	32 (91)	2 (6)	1 (3)
1-8 PD	8 (24)	24 (71)	2 (6)
>8 PD	0	8 (40)	12 (60)
Treatment Group = Patching (N=84)			
Distance tropia at 17 weeks			
Distance tropia at baseline	0 PD n (%)	1-8 PD n (%)	>8 PD n (%)
0 PD	49 (96)	2 (4)	0
1-8 PD	4 (19)	17 (81)	0
>8 PD	0	4 (33)	8 (67)
Near tropia at 17 weeks			
Near tropia at baseline	0 PD n (%)	1-8 PD n (%)	>8 PD n (%)
0 PD	45 (94)	2 (4)	1 (2)
1-8 PD	5 (24)	14 (67)	2 (10)
>8 PD	1 (7)	4 (27)	10 (67)

PD = Prism Diopter