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A Prospective Pilot Study of Treatment Outcomes for Amblyopia Associated With Myopic Anisometropia

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Objectives: To determine the efficacy of refractive correction alone and patching treatment with near activities on amblyopia associated with myopic anisometropia in children aged 4 to less than 14 years. The associations of visual acuity (VA) improvement with age, degree of anisometropia, patching compliance, presence of strabismus, and presence of eccentric fixation were also investigated.

Methods: Seventeen amblyopic children were recruited (range of VA in the amblyopic eye, 20/80 to 20/400). Visual acuity was assessed at 4, 8, 12, and 16 weeks while participants wore spectacles and/or contact lenses for full refractive correction. Patching treatment was initiated at the 16-week visit. The primary outcome was VA after 16 weeks of refractive correction alone and final VA after 16 weeks of patching.

Results: The mean (SD) baseline VA in the amblyopic eye was 0.96 (0.27) logMAR, which improved to a mean (SD) of 0.84 (0.24) logMAR with refractive correction and to a mean (SD) of 0.71 (0.30) logMAR after the addition of patching ($P < .001$). Comparing the final VA with

the baseline VA, we found that VA improvement averaged 2.59 lines. The final VA in the amblyopic eye was associated with the baseline VA in the amblyopic eye ($P < .001$), the magnitude of anisometropia ($P < .001$), and the level of patching compliance ($P = .04$). The improvement in VA with patching was inversely associated with participants' age ($P = .03$) and presence of eccentric fixation ($P = .02$).

Conclusion: Both refractive correction and patching significantly improved the VA of the amblyopic eye associated with myopic anisometropia, with 88% of participants' eyes improving 2 lines or more. Further improvement in VA was observed when patching plus near activities was added to refractive correction and patients were followed for 16 more weeks. We recommend that clinicians treat myopic anisometropic amblyopia with refractive correction and patching plus near activities.

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AMBLYOPIA IS THE MOST common cause of monocular visual impairment in children and young- and middle-aged adults.^{1,2} Anisometropia, as the most frequent cause of amblyopia, has been evaluated in numerous studies.³⁻⁵ However, anisometropia associated with high myopia was often excluded from those studies. Considering the limited studies of this type of amblyopia, there is controversy over refractive correction, treatment outcomes, and whether underlying structural abnormalities are present,⁶⁻¹² and some even question the value of attempting treatment at all.¹³

Reports on treating myopic anisometropic amblyopia are limited. Bangerter¹⁴ was the first to study treatment outcomes in patients with myopic anisometropic amblyopia. Using both pleoptic therapy and full-time patching, he reported a final visual acuity (VA) of 20/40

or better in 4 of his 16 patients (25%).¹⁴ The results in Rosenthal and von Noorden¹⁵ match the results in Bangerter,¹⁴ with 7 of 29 patients (24%) obtaining a final VA of 20/40 or better.¹⁵ Priestly et al¹⁶ treated 21 subjects using pleoptic therapy and full-time patching and reported a 14% success rate. This is lower than the success rate in Bangerter¹⁴ but consistent with the rate in Curtin and Schlossman¹⁷ (a 16% success rate in 25 subjects aged 3-17 years). More recently, Sen⁹ treated 55 myopic anisometropic amblyopes aged 5 to 22 years with both pleoptic therapy and full-time patching over a period of 4 months to 6 years. He reported that 31% of amblyopes had a final VA of 20/40 or better and that 58% had VA improvements of 2 lines or more. Kutschke et al¹⁸ retrospectively studied amblyopia caused by either myopic anisometropia or hyperopic anisometropia and reported that amblyopia with myopic anisometropia had a poorer vi-

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Table 1. Eligibility and Exclusion Criteria of Prospective Pilot Study of Treatment Outcomes for Amblyopia Associated With Myopic Anisometropia

Eligibility Criteria	Exclusion Criteria
Aged 4 to <14 years	Presence of ocular pathology causing reduced VA
Best-corrected VA in the amblyopic eye of 20/40 to 20/400 inclusive	Prior ocular surgery
Best-corrected VA in the fellow eye of 20/40 or better	Current vision therapy
Magnitude of myopic anisometropia of >3.00 D	Known skin reaction to patch or bandage adhesive
Intereye acuity difference of >3 logMAR lines	
Amblyopia associated with myopic anisometropia	
No amblyopia treatment (other than spectacles) in the past month and no more than 1 mo of amblyopia treatment in the past 6 mo	

Abbreviations: D, diopters; VA, visual acuity.

sual outcome (18 of 23 subjects [78%] reaching 20/40 or better) than amblyopia caused by hyperopic anisometropia (35 of 38 subjects [92%] reaching 20/40 or better) with full-time patching. Roberts and Adams¹⁹ retrospectively studied 6 children (aged 3-6 years) and reported that 3 had no VA improvement and that the other 3 had 2 lines or more of VA improvement with refractive correction and at least 2 hours of daily patching. Ghanem et al²⁰ performed laser in situ keratomileusis for 18 children followed by up to 24 months of patching treatment. Fourteen of these children had VA improvement of 3 lines or more with laser in situ keratomileusis and patching.²⁰ Despite the few studies showing that amblyopia treatment can be successful in myopic anisometropic amblyopia, it is still generally believed that amblyopia associated with myopic anisometropia is difficult to treat successfully. Many clinicians undercorrect the more myopic eye of these patients in order to allow the lenses to be more balanced optically and cosmetically, and they do not pursue further treatment.

The purpose of our study was to determine the efficacy of 16 weeks of refractive correction alone and an additional 16 weeks of refractive correction plus patching treatment with near activities for improving VA in amblyopia associated with myopic anisometropia in children aged 4 to 14 years. The association of VA improvement with age, degree of anisometropia, level of patching compliance, presence of strabismus, and presence of eccentric fixation were also investigated.

METHODS

STUDY POPULATION AND DATA COLLECTION

Both the study protocol and informed consent forms were approved by the institutional review board of the Illinois College of Optometry. In accordance with the guidelines of the Declaration of Helsinki, written informed consent was obtained from the parent or legal guardian of each child.

A total of 20 children diagnosed with myopic anisometropic amblyopia were recruited at the Illinois Eye Institute, an urban eye clinic, and 17 children completed the study; the other 3 children were lost to follow-up. All participants underwent a comprehensive eye examination, including a test for VA at far and near, a cover test at distance and near, a test for stereoacuity with both the Randot Preschool Stereoacuity Test and Stereo Fly (Stereo Optical Company, Inc), a test for manifest refraction, a dilated fundus examination with indirect ophthalmoscopy, cycloplegic refraction, monocular fixation using visuoscopy, and A-scan ultrasonographic biometry. Monocular distance VA was tested at 3 m (10 feet) using a computer-based electronic VA tester^{21,22} that is commonly used in amblyopia studies.^{23,24} Single-character optotypes with surrounding bars were used according to the Amblyopia Treatment Study VA protocol.²⁵ For children younger than 7 years, HOTV characters were used, and for children aged 7 years or older, Early Treatment Diabetic Retinopathy Study characters were used. Cycloplegia was induced with 1% cyclopentolate, 1% tropicamide, and 2.5% phenylephrine hydrochloride (1 drop each). Optical coherence tomography was performed on each child to rule out macular anomalies, including macular holes.¹² Other than refractive error and amblyopia, no participants had any concurrent ocular disease. Only 1 participant had ever worn spectacles for her refractive error. The eligibility and exclusion criteria are listed in **Table 1**.

Spherical difference between the eyes was corrected by a spherical contact lens (Focus Night & Day; CIBA Vision) in the more myopic eye, with the remaining refractive error corrected by the use of glasses. Visual acuity was assessed at baseline and at 4, 8, 12, and 16 weeks after participants began to wear a contact lens or spectacles for full refractive correction. At the baseline visit, VA and stereoacuity were tested 30 minutes after participants were fitted with a contact lens. Direct patching (patching of the fellow eye), 2 hours per day for moderate amblyopia (with a best-corrected VA of 20/40 to 20/80 in 2 of 17 participants) and 6 hours per day for severe amblyopia (with a best-corrected VA of 20/100 to 20/400 in 15 of 17 participants), was initiated 16 weeks after the initiation of refractive correction. A minimum of 30 minutes of daily near activities was prescribed for participants while undergoing patching treatment. Near activities included mazes, coloring of pictures, and school homework. The patching time was consistent throughout our study. The compliance with patching was monitored by asking the participants' parents or legal guardians to record the daily patching time. Compliance was categorized into 4 levels: excellent (75%-100% compliance with prescribed patching regimen), good (50%-74% compliance), fair (25%-49% compliance), and poor (<25% compliance). Visual acuity was assessed at 4 and 16 weeks after onset of patching. The time window for each follow-up visit was 2 weeks. The primary outcomes were VA after 16 weeks of refractive correction alone and final VA after 16 weeks of patching.

DATA ANALYSIS

To assess refractive error, the spherical equivalent was defined as the spherical power plus half of the minus cylinder power. Visual acuity was converted to logMAR for analysis. Stereoacuity scores in seconds of arc (Randot Preschool Stereoacuity Test) were converted to log values, and children with no detectable stereoacuity were assigned to the next test level (3.2 log seconds of arc) for analysis purposes. Arc seconds of stereoacuity from the Randot Preschool Stereoacuity Test corresponded to the following values in the log scale: 40" (1.60), 60" (1.78), 100" (2.00), 200" (2.30), 400" (2.60), 800" (2.90), and greater than 800" (3.20). The distributions of the spherical equivalent, the VA of the amblyopic eye, the VA of the fellow eye, age, the magnitude of anisometropia, and the axial

Table 2. Demographic Characteristics of 17 Participants in Prospective Pilot Study of Treatment Outcomes for Amblyopia Associated With Myopic Anisometropia

Characteristic	Participants, No. (%)
Female	10 (59)
Race	
African American	14 (82)
Hispanic or Latino	2 (12)
Asian	1 (6)
Age range, y	
4 to <7	6 (35)
7 to <14	11 (65)
Age, mean (SD), y	9.0 (3.0)

length were confirmed as normally distributed by use of the Kolmogorov-Smirnov test. A general linear model repeated-measures analysis was performed to assess the effect of 16 weeks of refractive correction alone and of refractive correction plus patching on VA improvement for an additional 16 weeks. The Pearson correlation was performed to evaluate the association of final VA and VA improvement with the following parameters: baseline VA, magnitude of anisometropia, and age. The effects of eccentric fixation and patching compliance on final VA and VA improvement were evaluated by the use of the Kendall τ correlation. The Wilcoxon signed rank test was performed to compare baseline stereoacuity to final stereoacuity measured with the Randot Preschool Stereoacuity Test. All data were analyzed using SPSS version 17.0 (SPSS Inc).

RESULTS

Table 2 shows the demographic characteristics for the amblyopic children. The baseline clinical characteristics of the participants are listed in **Table 3**. The mean (SD) baseline best-corrected VA was 0.96 (0.27) logMAR (mean Snellen fraction, 20/200; range, 20/80 to 20/400) in the amblyopic eye and 0.12 (0.11) logMAR (mean Snellen fraction, 20/25) in the fellow eye. The mean (SD) spherical equivalent refractive error in the amblyopic eyes was -10.65 (3.28) diopters (D), with a range of -5.00 to -15.75 D, whereas the mean (SD) spherical equivalent in the nonamblyopic fellow eyes was -1.28 (2.60) D, with a range of $+1.25$ to -7.88 D. The mean (SD) magnitude of anisometropia (spherical equivalent) was -9.37 (3.57) D, with a range of -3.63 to -14.88 D. The mean (SD) axial length was 26.61 (1.45) mm in the amblyopic eyes and 23.23 (1.26) mm in the fellow eyes. The magnitude of anisometropia was significantly correlated with the interocular difference in axial length ($r=0.98$, $P<.001$). Thirteen children had pure myopic anisometropic amblyopia, and 4 children had combined-mechanism amblyopia (strabismus and myopic anisometropia).

The mean (SD) VA in the amblyopic eyes significantly improved to 0.84 (0.24) logMAR (mean Snellen fraction, 20/138) ($P<.001$) with 16 weeks of refractive correction alone and to 0.71 (0.30) logMAR (mean Snellen fraction, 20/100) ($P<.001$) after 16 weeks of patching. Further improvement in VA was observed with the additional 16 weeks of treatment with refractive correction plus patching and near activities. **Table 4** shows

Table 3. Baseline Clinical Characteristics of 17 Participants in Prospective Pilot Study of Treatment Outcomes for Amblyopia Associated With Myopic Anisometropia

Characteristic	Participants, No. (%)
VA in amblyopic eye	
20/80	2 (12)
20/100	4 (24)
20/125	2 (12)
20/250	3 (18)
20/320	4 (24)
20/400	2 (12)
VA, mean (SD), logMAR	0.96 (0.27)
Spherical equivalent in amblyopic eye, D	
-5 to >-10	6 (35)
-10 to >-15	9 (53)
<-15	2 (12)
Mean (SD)	-10.65 (3.28)
Magnitude of anisometropia, D	
-3 to >-5	1 (6)
-5 to >-10	8 (47)
-10 to >-15	8 (47)
Mean (SD)	-9.37 (3.57)
Constant strabismus	
Yes	4 (24) ^a
No	13 (76)
Fixation (visuoscopy)	
Central steady	11 (65)
Central unsteady	3 (18)
Eccentric fixation	3 (18)
History of patching (>1 mo)	
Yes	3 (18)
No	14 (82)

Abbreviations: D, diopters; CLXT, constant left exotropia; CRET, constant right esotropia; CRXT, constant right exotropia; VA, visual acuity; Δ , prism diopters.

^aFour subjects had strabismus: participant 2 (18 Δ CRXT, 8 Δ CRXT'); participant 4 (14 Δ CLXT, 8 Δ CLXT'); participant 8 (12 Δ CLXT, 12 Δ CLXT'); and participant 9 (6 Δ CRET, 6 Δ CRET').

Table 4. VA in the Amblyopic Eyes of 17 Children After 16 Weeks of Refractive Correction and 16 Weeks of Patching

Improvement From Baseline	Participants, No. (%)	
	Refractive Correction	Patching
0 lines	5 (29)	1 (6)
1 line	5 (29)	1 (6)
2 lines	6 (35)	6 (35)
3 lines	0 (0)	7 (41)
4 lines	1 (6)	0 (0)
5 lines	0 (0)	2 (12)
Lines, mean (SD)	1.24 (1.09)	2.59 (1.23)

Abbreviation: VA, visual acuity.

the line improvement of VA by refractive correction and patching compared with the baseline VA. After 16 weeks of refractive correction alone, VA in the amblyopic eyes ranged from 20/63 to 20/320 with no participant having amblyopia resolved. A mean (SD) of 2.59 (1.23) logMAR lines of VA improvement was observed with refractive correction and patching. The cumulative distribution of baseline VA vs final VA in the amblyopic eyes is shown in **Figure 1**. The patching compliance of our

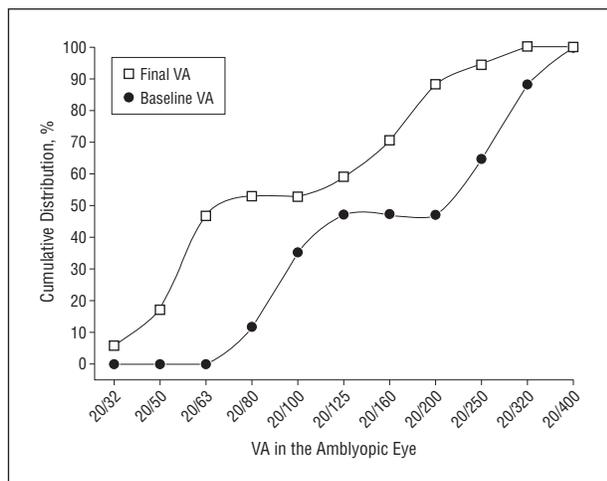


Figure 1. Cumulative distribution of baseline visual acuity (VA) vs final VA in the amblyopic eyes of 17 children (aged 8 to <14 years).

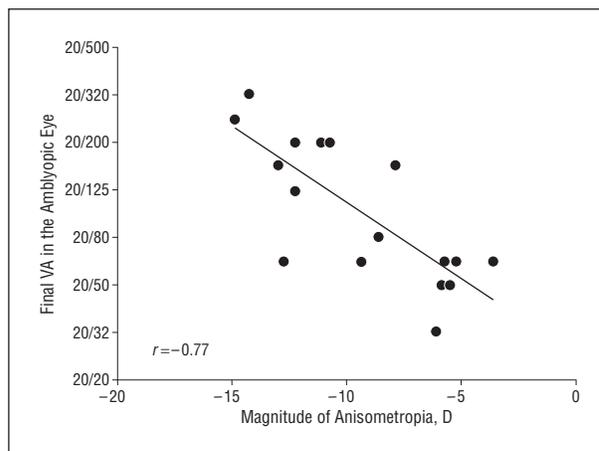


Figure 3. Correlation between the magnitude of anisometropia and final visual acuity (VA) in the amblyopic eyes of 17 children (aged 8 to <14 years). D indicates diopters.

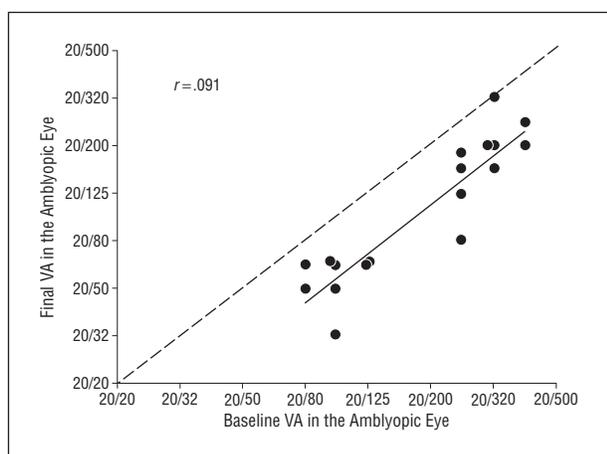


Figure 2. Correlation between baseline visual acuity (VA) and final VA in the amblyopic eyes of 17 children (aged 8 to <14 years). The black circles below the dashed line represent participants whose final VA improved from baseline (16 participants); the black circle on the dashed line represents the single participant whose final VA was the same as the baseline VA.

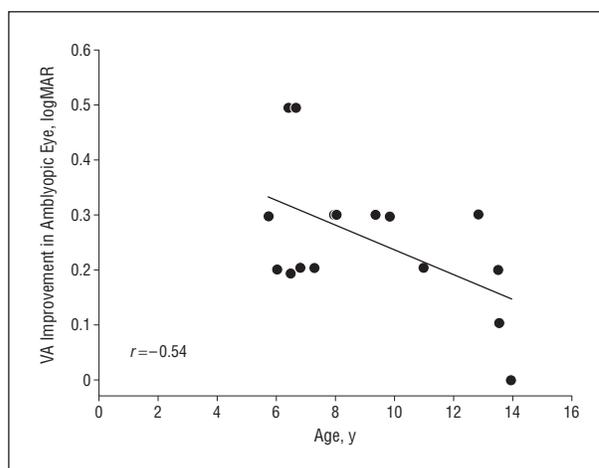


Figure 4. Correlation between the age of participants and visual acuity (VA) improvement in the amblyopic eyes of 17 children (aged 8 to <14 years).

17 participants was 41% ($n=7$) in the excellent category, 47% ($n=8$) in the good category, 12% in the fair category ($n=2$), and 0% in the poor category.

At the end of 16 weeks of patching, 8 participants (47%) had a VA of 20/63 or better; 9 (53%) had 3 lines or more of VA improvement, and 15 (88%) had 2 lines or more of VA improvement. Stereoacuity improved for 8 participants, with 4 participants' stereoacuity improving from nil to positive with Stereo Fly (with negative response to the Randot Preschool Stereoacuity Test) and 4 participants' stereoacuity improving on the Randot Preschool Stereoacuity Test. A mean (SD) of 0.17 (0.35) log seconds of arc improvement on the Randot Preschool Stereoacuity Test was observed for our participants. However, no significant difference was detected ($P=.68$) when we compared the final stereoacuity with the baseline stereoacuity. The final VA in the amblyopic eyes was statistically significantly associated with the baseline VA ($r=0.91$, $P<.001$) (**Figure 2**), the magnitude of anisometropia ($r=-0.77$, $P<.001$) (**Figure 3**), and patching compliance ($r=0.44$,

$P=.04$) but not with age or presence of eccentric fixation. The amount of VA improvement with patching in the amblyopic eye was inversely associated with participants' age ($r=-0.54$, $P=.03$) (**Figure 4**) and the presence of eccentric fixation ($r=-0.52$, $P=.02$) but not with baseline VA ($r=0.05$, $P=.99$), the magnitude of anisometropia ($r=0.06$, $P=.82$), or final VA ($r=-0.40$, $P=.11$). Despite the age effect, 4 of our 8 older children (aged 8 to <14 years) had significant VA improvement (3 lines or more). There was no correlation between VA improvement following 16 weeks of refractive correction and VA improvement with an additional 16 weeks of refractive correction plus patching and near activities ($r=0.35$, $P=.17$).

In an effort to ascertain whether the presence of strabismus in addition to anisometropia had an effect on amblyopia treatment outcomes, the VA improvement in the amblyopic eye was compared between the children with purely myopic anisometropia ($n=13$) and the children with combined-mechanism amblyopia (myopic anisometropia and strabismus) ($n=4$). More VA improvement was identified in the pure myopic anisometropic group (0.29 logMAR, 2.92 lines) than in the

combined-mechanism group (0.15 logMAR, 1.50 lines) ($P = .04$).

COMMENT

We found that both 16 weeks of refractive correction and 16 weeks of patching with near activities significantly improved the VA of the amblyopic eye associated with myopic anisometropia in children aged 4 to 14 years, with further VA improvement when patching and near activities were added to refractive correction. Our study was not designed to determine whether this further improvement resulted from the patching and near activities specifically or from the additional time wearing the spectacles and/or contact lenses for refractive correction. In addition, we found that the amount of VA improvement by refractive correction and patching was inversely associated with the age of the participant and presence of eccentric fixation. More VA improvement was identified in the pure myopic anisometropic group than in the combined-mechanism group (myopic anisometropia and strabismus).

Amblyopia associated with myopic anisometropia has been reported to be the least responsive subtype of anisometropic amblyopia to treatment.¹⁸ Several studies^{9,14-16,18,19,26} regarding the treatment outcomes for myopic anisometropia demonstrated inconsistent results, with the percentage of subjects achieving VA improvement to 20/40 or better varying from 14% to 78%. The previous studies of myopic anisometropic amblyopia had the following limitations:

- The patching time varied between subjects, with full-time patching commonly prescribed.
- The duration of patching varied from months to years and was not well controlled within each study or between studies.
- Different VA measurements were used, varying from Allen cards to the Snellen eye chart, single line, to the Snellen eye chart, single letter. Some studies used different charts to check VA before and after amblyopia treatment.
- The duration of refractive correction was not defined.
- Treatment outcomes and effects of possible associated factors on treatment such as age and presence of strabismus were stated as percentages without formal statistical analysis.
- Treatment compliance was not reported in most of the studies.

In contrast, our study was prospective, with the following conditions well controlled: enrollment criteria, duration of refractive correction, patching time, activity while patching, and follow-up schedule. Additionally, the duration of patching in our study was consistent, 16 weeks for every participant. The treatment outcomes were measured at the end of 16 weeks of patching. This protocol is different from the previous studies in which subjects were treated until there was no further VA improvement and in which the maximum VA was used to measure the outcomes. Thus, our treatment outcomes cannot be compared with those in previous studies.

Besides the well-controlled study design, our study has the following advantages over the previous ones. First, the VA measurement method in our study, a computer-based electronic VA tester with single optotypes and surrounding bars, has high test-retest reliability^{21,27} and is validated for use in amblyopia studies.^{23,24} This measurement is more appropriate for amblyopia studies than the methods used in previous studies. Second, contact lenses were used in our study to correct the anisometropia; this modality may help participants tolerate the refractive correction better and improve their compliance. Without the use of contact lenses, a majority of our participants likely would have experienced aniseikonia and poor cosmetic appearance. One of the authors (Y.P.) is conducting a prospective study to compare the treatment outcomes for amblyopia with refractive error corrected by contact lenses vs spectacles, which will provide more information on the contact lens treatment option. Finally, part-time patching instead of full-time patching was prescribed in our study. One potential advantage of part-time patching is that it may improve patching compliance. The Pediatric Eye Disease Investigator Group found that part-time patching was as effective as full-time patching in both anisometropic and strabismic amblyopia.⁴ Subjects with high myopia were excluded from their studies. To determine which patching method should be used in myopic anisometropic amblyopia, an additional study is warranted to compare the treatment outcomes between part-time and full-time patching.

The Pediatric Eye Disease Investigator Group studied 507 amblyopic subjects aged 7 to 17 years and reported that younger age was associated with greater VA improvement.²⁸ Pollard and Manley²⁶ reported (without any statistical analysis) no age effect on amblyopia treatment in their 40 amblyopic children aged 2 to 14 years with myopic anisometropia. With 55 subjects aged 7 to 22 years, Sen⁹ concluded that, although younger subjects aged 7 to 14 years showed improved VA more often (63.8%) than those aged 15 to 22 years (47.3%), the difference in improvement amount between the 2 groups was not significant. Our finding that the amount of VA improvement was significantly associated with age is consistent with the findings of the Pediatric Eye Disease Investigator Group but different from previous studies on myopic anisometropia.

We found that participants with combined-mechanism amblyopia had less VA improvement than those with pure myopic anisometropic amblyopia. We had only 4 participants in the combined-mechanism group. A future study with more participants is necessary to confirm whether the presence of strabismus in addition to myopic anisometropia has an effect on amblyopia treatment outcomes. But, interestingly, all of the participants with combined-mechanism amblyopia had abnormal monocular fixation, 2 with eccentric fixation and 2 with unsteady central fixation, compared with 11 of the 13 with pure myopic anisometropic amblyopia having steady central fixation. Furthermore, we found that the presence of eccentric fixation was inversely correlated with VA improvement in the amblyopic eye. Monocular fixation has not been commonly investigated in the recent amblyopia studies.^{4,24,29,30} Our results indicate that abnormal monocular fixation may be useful as a predictor of treatment outcomes in amblyopia associated with myopic anisometropia.

There are some limitations to our study. First, there were a small number of participants enrolled. A study with more participants would provide stronger evidence for treatment outcomes on myopic anisometropic amblyopia. Second, based on the small number of participants, univariate analysis was used; therefore, the effect of each risk factor on VA improvement can be confounded by another risk factor. Third, the participants were enrolled at 1 clinical site, which may limit the ability to generalize the results to other clinical settings. The single participant with a previous spectacle correction for 3 months was not excluded from our study. This may affect the treatment outcomes based on duration of spectacle correction. Finally, treatment outcomes following 16 weeks of refractive correction alone and 16 weeks of patching were investigated in our study. It would be interesting to study the effect of a longer duration of refractive correction and patching on treatment outcomes for myopic anisometropic amblyopia.

In summary, both the 16 weeks of refractive correction and the 16 weeks of patching with near activities improved the VA of the amblyopic eye associated with myopic anisometropia in children aged 4 to 14 years. Further improvement in VA was observed when patching plus near activities was added to refractive correction and when patients were followed for 16 additional weeks. With refractive correction and part-time patching, 53% of our amblyopic children had VA improvements of 3 lines or more, and 88% had 2 lines or more of improvement. Based on our findings, we recommend that clinicians actively treat myopic anisometropic amblyopia with refractive correction and patching plus near activities. We suggest treating this type of amblyopia with refractive correction initially, which might potentially make patching treatment easier, and subsequently adding patching and near activities when VA improvement reaches a plateau. Because age was found to be significantly associated with VA improvement in the amblyopic eye, we recommend that clinicians treat this condition in a timely fashion.

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