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Effect of Ocular Alignment on Emmetropization in Children <10 years with Amblyopia

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Abstract

Purpose—To determine whether change in refractive error is associated with ocular alignment in 105 children 3 to <7 years of age who previously participated in a randomized trial comparing atropine and patching for moderate amblyopia.

Design—Prospective cohort study

Methods—One hundred five children 3 to <7 years of age previously participated in a randomized trial comparing atropine with patching for moderate amblyopia. Cycloplegic refraction was measured at baseline and 10 years of age. Ocular alignment at baseline was categorized as orthotropic, microtropic (1–8Δ horizontal tropia), or heterotropic (>8Δ horizontal tropia). Multivariate regression models evaluated whether change in spherical equivalent refractive error was associated with alignment category, after adjusting for age, baseline spherical equivalent refractive error, and type of amblyopia treatment.

Results—Between enrollment and the age 10-year exam there was a decrease in spherical equivalent refractive error from hyperopia to less hyperopia (amblyopic eye: − 0.65D, 95%CI −0.85, −0.46; fellow eye: −0.39D, 95%CI −0.58, −0.20). A greater decrease in amblyopic eye refractive error was associated with better ocular alignment category (p=0.004), with the greatest

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Disclosure

Statement about Conformity with Author Information: The study protocol and informed consent forms were prospectively approved by an institutional review board (Jaeb Center for Health Research, Tampa, FL or the institutional review board of the respective institution where the subjects were recruited and treated). Written informed consent was obtained from the parent or legal guardian before participation in the study or undergoing any study procedure. This clinical trial was conducted in accordance with Good Clinical Practices, the World Health Organization Declaration of Helsinki 1996, and the Health Insurance Portability and Accountability Act. The original clinical trial was registered on the www.clinicaltrials.gov website, identifier NCT00000170.
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decrease occurring in orthotropic patients. There was no relationship between ocular alignment category and change in fellow-eye refractive error.

Conclusions—Among children treated for anisometropic, strabismic, or combined mechanism amblyopia, there is a decrease in amblyopic eye spherical equivalent refractive error to less hyperopia after controlling for baseline refractive error. This negative shift toward emmetropia is associated with ocular alignment, which supports the suggestion that better motor and sensory fusion promote emmetropization.

Introduction

In a clinical trial conducted by the Pediatric Eye Disease Investigator Group (PEDIG) of 3- to <7-year-old children with moderate amblyopia from anisometropia, strabismus, or both combined, prescribing patching or atropine treatment resulted in similar improvement in visual acuity after 2 years, and the improvement was still present at 10 years of age.[1] In addition, up to 2 years of atropine treatment was not associated with an adverse effect on refractive development, when compared with patching.[2]

It has been proposed that strabismus itself may affect axial growth of the eye and refractive error development.[3] Because many patients with amblyopia have strabismus, we questioned whether ocular alignment is associated with the change in amblyopic eye spherical equivalent refractive error in individuals with amblyopia followed to age 10 years who were previously treated with atropine and/or patching.

Methods

The study protocol has been detailed elsewhere,[4,5] is available on the PEDIG website (www.pedig.net), and is summarized at www.clinicaltrials.gov under the identifier NCT00000170. A brief summary of the protocol follows.

Primary eligibility criteria for the multicenter randomized trial included age less than 7 years, visual acuity in the amblyopic eye of 20/40 to 20/100, visual acuity in the fellow eye of 20/40 or better, interocular acuity difference of 3 or more logarithm of minimal angle of resolution (logMAR) lines, no myopia (−0.50 diopters (D) or more spherical equivalent refractive error) in either eye and the presence or history of an amblyopiogenic factor meeting the study-specified criteria for strabismus and/or anisometropia.

After wearing any needed refractive correction for at least 4 weeks, subjects were randomized to either patching (6 hours up to full-time every day at investigator discretion) or atropine (1%, 1 drop once daily) for 6 months. A primary outcome examination was performed 6 months after randomization. Between 6 months and 2 years post randomization, treatment was at investigator discretion.

At the time of the 2-year visit, parents of subjects from a subset of participating sites (those with more than 5 subjects enrolled and continuing with other PEDIG protocols) were invited to enter a long-term extension phase. All treatment during this phase was prescribed at investigator discretion. Of the 419 subjects in the trial, 188 consented to participate, and 176 completed the age 10-year extension exam. Testing at the age 10-year exam included measurement of visual acuity in each eye (measured by a study-certified examiner with the Electronic Early Treatment of Diabetic Retinopathy Study testing protocol©),[6] cycloplegic refraction (within the prior 6 months), measurement of ocular alignment using the simultaneous prism and cover test at distance and near fixation, and assessment of random dot stereoacuity using the Preschool Randot. At enrollment, alignment was measured with correction, if prescribed, and recorded as either orthotropic, microtropic (1–8 prism diopters

(Δ) horizontal tropia), or heterotropic (>8 Δ horizontal tropia) based on the maximum angle measured at distance or near. Visual acuity was measured using the ATS-HOTV protocol[7] on the Baylor Video Acuity Tester (BVAT; Mentor O&O Inc., Norwell, MA) or Electronic Visual Acuity Tester (EVA).[8]

To be included in the current analyses, subjects needed to meet the following additional criteria: have a cause of amblyopia due to anisometropia, strabismus, or both (2 subjects with indeterminate cause were excluded) and have a cycloplegic refraction at or within 6 months of their 10th birthday (age 9.5 to 10.5 years). Sixty-nine subjects without a cycloplegic refraction within this age window were excluded. Of the 176 subjects completing the age 10-year exam, 105 met these additional criteria, and were included for analysis. Because subjects were enrolled between age 3 and less than 7 years, the length of follow-up until the age 10-year examination ranged from 3.1 to 7.3 years (mean of 5.0 years).

Statistical Methods

Subject characteristics for those included in these analyses versus those not included were compared to evaluate potential selection bias. The primary outcome for analysis was total change in spherical equivalent refractive error in the amblyopic eye between baseline and age 10 years. Positive values of change indicated a shift in the positive (more hyperopic) direction, while a negative value indicated a shift in the negative (less hyperopic and more myopic) direction. Change from baseline to age 10 years was evaluated in each eye by computing descriptive statistics and 95% confidence intervals (CI). All additional analyses were adjusted for baseline spherical equivalent refractive error as a potential confounder.

A multivariate linear regression model adjusting for age at randomization, baseline spherical equivalent refractive error, and amblyopia treatment prescribed at randomization was used to evaluate the association of change in spherical equivalent refractive error in each eye with ocular alignment categorization at baseline. Baseline spherical equivalent refractive error and age at randomization were treated as continuous variables (linearity assumptions were evaluated prior to fitting the final model). Ocular alignment at baseline was categorized into one of the three categories of alignment/misalignment based on the maximum angle of deviation at either distance or near fixation, as either orthotropic (0 Δ), microtropic (1 to 8 Δ), or heterotropic (>8 Δ) (Table 1). To control the type I error rate, pair-wise comparisons between each of the ocular alignment categories were performed using the Tukey-Kramer adjustment for multiple comparisons only if the F-test for ocular alignment showed an association. A 95% CI and descriptive statistics were used to evaluate the difference in change in spherical equivalent refractive error between the eyes. Mean change in amblyopic eye spherical equivalent refractive error stratified by baseline amblyopic eye spherical equivalent refractive error and anisometropia at baseline was calculated overall and by each category of baseline ocular alignment to evaluate whether there was an association between change in amblyopic eye refractive error and baseline ocular alignment controlling individually for baseline amblyopic eye refractive error and baseline anisometropia (Table 2). The effect of tropia status on change in amblyopic eye spherical equivalent refractive error within categories of baseline amblyopic eye spherical equivalent refractive error was examined to evaluate potential interaction. In a separate analysis on each eye, an integer value was assigned to each category of ocular alignment to evaluate trend (Table 1 and Supplemental Table 1). The association between stereoacuity at age 10 years and baseline ocular alignment was evaluated using descriptive statistics and an exact Wilcoxon rank sum test. Analyses were performed using SAS Version 9.1 (SAS Institute, Cary, NC).

Results

Demographics of Cohort

The median age of the 105 subjects at randomization was 5.2 years (range 2.6 to 7.0 years). At enrollment, median amblyopic eye visual acuity was 20/63 (range 20/40 to 20/125[4]); median fellow eye visual acuity was 20/25 (range 20/16 to 20/40); median amblyopic eye spherical equivalent refractive error was +4.50D (range 0.00 to +8.75D); and median fellow eye spherical equivalent refractive error was +2.50D (range 0.00 to +8.00D). Of the 58 subjects with a tropia at enrollment, 51 (88%) had esotropia, 5 (9%) had exotropia, and 2 (3%) had a horizontal tropia where the direction was not recorded. The cohort for analysis was comparable to the 314 randomized subjects who were not included in this analysis by race, gender, cause of amblyopia (anisometropia, strabismic, or combined-mechanism), baseline visual acuity in the amblyopic and fellow eyes, baseline interocular acuity difference, baseline mean spherical equivalent refractive error, and prior treatment before randomization. Nevertheless, subjects who were included in the present analysis were slightly younger (median age 5.2 years versus 5.4 years), had better amblyopic eye visual acuity at the 2-year outcome exam (median visual acuity = 20/25 versus 20/32), and were more often assigned atropine at randomization (52% versus 47%) than subjects who were not included.

At the age 10-year examination, the median age was 10.1 years (range 9.5 to 10.5 years); median amblyopic eye visual acuity was 20/25 (range 20/16 to 20/125); median fellow eye visual acuity was 20/20 (range 20/12 to 20/50); median amblyopic eye spherical equivalent refractive error was +4.00D (range −1.50 to +8.25D); and median fellow eye spherical equivalent refractive error was +1.88D (range −2.00 to +8.00D). The median stereoacuity at age 10 years was 100 seconds of arc in subjects with orthotropia at enrollment, >800 seconds of arc in subjects with microtropia at enrollment, and >800 seconds of arc in subjects with heterotropia at enrollment (Table 3). Subjects with orthotropia at enrollment had better stereoacuity at age 10 years compared to subjects without orthotropia ($p < 0.001$).

Change in Refractive Error

Between enrollment and the age 10-year exam there was a decrease in spherical equivalent hyperopia refractive error in the amblyopic eye with a mean change of −0.65D (95% CI= −0.85 to −0.46) over that time period. This decrease was associated with better ocular alignment category ($p=0.004$), with the greatest decrease found in subjects who were orthotropic at baseline (adjusted for age at randomization, baseline amblyopic eye spherical equivalent refractive error, and amblyopia treatment prescribed at randomization). Adjusted mean change in amblyopic eye spherical equivalent refractive error was −1.01D (95% CI= −1.29, −0.72) in the subjects with orthotropia at baseline, −0.51D (95% CI= −0.88, −0.15) in those with microtropia, and −0.21D (95% CI= −0.58, 0.17) in those with heterotropia greater than 8Δ (Table 1). This decrease in effect across the categories of ocular alignment (from orthotropia to heterotropia) also occurred within categories of baseline amblyopic eye spherical equivalent refractive error and anisometropia at baseline (Table 2). The effect of eye alignment did not differ by baseline amblyopic eye spherical equivalent refractive error ($p=0.92$).

Decreasing mean hyperopic spherical equivalent refractive error (−0.39D; 95% CI= −0.58, −0.20) also was observed in the fellow eye, between enrollment and the 10-year exam. The change was similar among subjects with orthotropia, microtropia, and heterotropia greater than 8Δ at baseline (Supplemental Table 1). In the 64 subjects with anisometropia at baseline, the decrease in spherical equivalent hyperopia refractive error was on average 0.61D greater in the amblyopic eye then the fellow eye (95% CI= 0.37, 0.86).

Discussion

We evaluated change in amblyopic eye refractive error in 105 (104 hyperopic, 1 emmetropic) children who were treated with the appropriate refractive correction followed by occlusion or atropine for strabismic, anisometropic, or combinedmechanism amblyopia at age 3–<7 years and followed to age 10 years. We found a negative shift in amblyopic eye spherical equivalent refractive error. The shift was small, so that the majority of subjects remained hyperopic in each eye at age 10 years. A greater decrease in amblyopic eye spherical equivalent refractive error was associated with better ocular alignment, with the greatest decrease observed in those with orthotropia at baseline, and smallest decrease in those with a heterotropia greater than 8Δ.

Previous studies have reported a similar, small overall negative shift,[9–12] although methodological differences prevent a direct comparison of results (e.g. retrospective design, sample size, and/or differences in subject age, distribution of baseline refractive error, duration of follow-up, type of cycloplegic agent used and/or ocular alignment status).

We found that ocular alignment/misalignment appears to influence the change in amblyopic eye refractive error, with subjects having greater than 8Δ of heterotropia showing negligible change in refractive error, whereas orthotropic subjects had a significantly larger decrease in their hyperopia. All the children in this study were initially amblyopic and it is not known if the findings would be the same in nonamblyopic strabismic children. Our findings are consistent with previous reports that children who are strabismic at an early age often fail to show normal emmetropization[13–17]

Interestingly, the mean negative shift of amblyopic eye refractive error in subjects with microtropia was intermediate between orthotropic and heterotropic subjects (though not statistically different from either). One important difference between amblyopic children with heterotropia, microtropia, and orthotropia is their degree of binocularity. Bifoveal fusion is only present in individuals with orthotropia and true random dot stereoacuity is not consistent with heterotropia (>8Δ),[18] therefore it is possible that better motor and sensory fusion allow or promote the emmetropization process, through mechanisms that are yet to be elucidated. Whatham and Judge found that in monkeys, emmetropization was compromised when rotating prisms were used experimentally to induce ocular misalignment and to encourage a preference for fixation with the contralateral eye,[19] suggesting that ocular alignment, and in particular fixation may be an important factor in emmetropization. Unfortunately, we did not evaluate fixation preference.

Strengths of the present study include a prospective study design, inclusion of a large, well-defined cohort of subjects with anisometropic, strabismic and combinedmechanism amblyopia, and follow up for a mean of 5 years. Limitations of our study include exclusion of subjects with myopia and severe amblyopia from the original randomized clinical trial. Therefore, our results cannot be generalized to those children.

In conclusion, hyperopic children treated for amblyopia associated with anisometropia, strabismus, or both combined undergo a negative shift in refractive error in their amblyopic eye, from hyperopia toward less hyperopia. Despite the negative shift, most eyes remain hyperopic at 10 years of age. The negative shift toward emmetropia in amblyopic eyes with hyperopia is associated with eye alignment with smaller shifts observed in children who had heterotropia greater than 8Δ, which supports the suggestion that better motor and sensory fusion promote emmetropization.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Change in Amblyopic Eye Spherical Equivalent Refractive Error from Baseline to Age 10 Years by Category of Ocular Alignment at Baseline

Category of Ocular Alignment[a] at Baseline	Change in Amblyopic Eye Spherical Equivalent Refractive Error		
	N	Mean[b]	95% Confidence Interval
1:Orthotropia (0 Δ)	47	−1.01§	(−1.29, −0.72)
2:Microtropia (1–8 Δ)	29	−0.51§, ‡	(−0.88, −0.15)
3:Heterotropia (>8 Δ)	29	−0.21‡	(−0.58, 0.17)
P-value (baseline ocular alignment score)[c]	0.001		

[a]Maximum angle of deviation measured in correction, if prescribed, determined using the simultaneous prism and cover test at distance and near fixation

[b]Adjusted for baseline amblyopic eye spherical equivalent refractive error, age at randomization, and treatment prescribed at randomization (baseline spherical equivalent refractive error and age at randomization were treated as continuous variables; treatment prescribed was either patching or atropine)

[c]From a model with an ordinal ocular alignment score (1, 2, or 3) with adjustments for baseline amblyopic eye spherical equivalent refractive error, age at randomization, and treatment prescribed at randomization (baseline spherical equivalent refractive error and age at randomization were treated as continuous variables; treatment prescribed was either patching or atropine)

§,‡If the same symbol is listed for any two categories of ocular alignment, there is no statistical difference in change in amblyopic eye spherical equivalent refractive error

Δ= prism diopter
D= diopters

Table 2

Change in Amblyopic Eye Spherical Equivalent Refractive Error from Baseline to Age 10 Years by Category of Ocular Alignment at Baseline and Baseline Amblyopic Eye Spherical Equivalent or Baseline Anisometropia

	Alignment at Baseline[a]											
	Overall			Ortho (0 Δ)			Micro (1–8 Δ)			Hetero (>8 Δ)		
	Change in *Amblyopic Eye* Spherical Equivalent											
	n	Mean	Std	n	Mean	Std	n	Mean	Std	n	Mean	Std
Amblyopic Eye Spherical Equivalent at Baseline												
Overall	105	−0.65	1.02	47	−1.01	1.07	29	−0.55	0.80	29	−0.19	0.94
<2 D	12	−0.36	0.71	2	−1.44	0.80	4	−0.28	0.65	6	−0.06	0.40
2 to <3 D	9	−0.36	0.74	4	−0.38	0.98	1	−0.75	---	4	−0.25	0.65
3 to <4 D	17	−0.53	0.95	7	−0.91	0.90	3	−0.44	0.53	7	−0.20	1.10
4 to <5 D	22	−0.97	1.29	13	−1.32	1.22	4	−0.63	0.88	5	−0.35	1.65
5 to <6 D	16	−0.36	1.24	5	−0.55	1.91	7	−0.63	0.79	4	0.34	0.79
6 to <7 D	16	−0.88	0.76	10	−1.03	0.61	5	−0.70	1.09	1	−0.38	---
≥7 D	13	−0.82	0.88	6	−1.06	0.84	5	−0.48	1.08	2	−0.94	0.27
Anisometropia at Baseline												
Overall	105	−0.65	1.02	47	−1.01	1.07	29	−0.55	0.80	29	−0.19	0.94
<0 D	7	−0.45	0.63	1	−0.88	---	2	−0.63	0.88	4	−0.25	0.64
0 to <1 D	40	−0.27	0.91	5	−0.70	0.88	12	−0.27	0.64	23	−0.17	1.03
1 to <2 D	13	−0.67	0.80	7	−0.66	1.02	4	−0.94	0.46	2	−0.19	0.27
2 to <3 D	16	−1.29	1.35	13	−1.24	1.49	3	−1.48	0.49	0	---	---
3 to <4 D	15	−0.90	1.05	9	−1.14	0.97	6	−0.54	1.15	0	---	---
≥ 4 D	14	−0.85	0.80	12	−0.99	0.76	2	0	0.35	0	---	---

[a]Maximum angle of deviation measured with correction, if prescribed, determined using the simultaneous prism and cover test at distance and near fixation

Δ = prism diopter
D = diopter
Std = Standard Deviation

Table 3

Stereoacuity at Age 10 Years versus Ocular Alignment at Enrollment

	Ocular Alignment at Enrollment		
Stereoacuity at age 10 years (seconds of arc)	**Orthotropia (0 Δ) N=47**	**Microtropia (1–8 Δ) N=29**	**Heterotropia (>8 Δ) N=29**
40	10	2	0
60	5	2	0
100	10	1	2
200	6	3	1
400	6	2	1
800	1	1	2
>800	9	14	17
Failed pretest/Test not done	0	4	6
Median (25^{th}, 75^{th} %ile)	100 (60, 400)	>800 (200, >800)	>800 (800, >800)
P-Value *		<0.001	

* From an exact Wilcoxon rank sum test for the difference in distribution of stereoacuity (logarithm of seconds of arc) in subjects with orthotropia at enrollment versus subjects without orthotropia at enrollment (subjects with microtropia or heterotropia)