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## Lack of Concordance between Fixation Preference and HOTV Optotype Visual Acuity in Preschool Children: the Baltimore Pediatric Eye Disease Study

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### Abstract

**Objective**—To compare the results of fixation preference testing and standardized visual acuity testing in White and African-American children aged 30 through 71 months.

Design—Cross-sectional study.

**Participants**—The Baltimore Pediatric Eye Disease Study is a population-based evaluation of the prevalence of vision disorders in children aged 6 through 71 months in Baltimore, Maryland, United States. A total 1,714 children 30 through 71 months of age were eligible for inclusion in this report, with 1435 (83.7%) testable by both fixation preference and Amblyopia Treatment Study (ATS) visual acuity protocol.

**Methods**—The vision of all children 30 through 71 months of age was tested using both the ATS visual acuity testing protocol (using single HOTV symbols with surround bars) and fixation preference testing (FPT).

**Main Outcome Measures**—The ability of fixation preference testing to identify children with clinically important inter-ocular differences (IOD) in visual acuity (i.e., two or more logMAR [logarithm of minimum angle of resolution] difference or greater).

**Results**—Fifty-three children had two or more lines of IOD in visual acuity. Seven of them were graded as having "Momentary" or "No Fixation" (sensitivity =13.2% [95% CI (confidence interval) = 5.3, 27.2]), while 45 were graded as "Normal" by FPT. In all 7 of the cases of poor FPT, the betterseeing eye was preferred. Low sensitivity and high specificity for detecting an IOD of two or more lines with FPT were seen for both White (33.3% sensitivity [95% CI = 9.5, 57.2)], 99.6% specificity [95% CI = 98.7, 100]) and African American (6.5% sensitivity [95% CI = 0.6, 23.2], 99.3% specificity [95% CI = 98.3, 99.8]) children. When assessing FPT performance for 3 or more lines of IOD, only 5 of the 20 children (sensitivity = 25% [95% CI = 6.0, 44.0] had FPT grades of "Momentary" or "No Fixation."

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Fixation preference testing, in a population-based research project, does not accurately identify preschool children with two or more lines of interocular difference in presenting visual acuity. Its use for diagnosis and monitoring should be reconsidered.

**Conclusions**—FPT, when used as part of a population-based research project, does not accurately identify preschool children with two or more lines of interocular difference in presenting visual acuity. The clinical value of this test is poor and its use for diagnosis and monitoring interventions should be reconsidered.

### Keywords

visual acuity; children; prevalence

### Introduction

Fixation preference testing (FPT) is a standard tool for assessing pre-verbal children for the presence of amblyopia.<sup>1-5</sup> FPT assumes that children with amblyopia will prefer the better-seeing eye when the two eyes are dissociated. To perform FPT the eyes may be dissociated by an existing strabismus or a strabismus can be simulated with a prism held before one eye.

Zipf reported that FPT correctly identified amblyopia in children with large angle strabismus, but falsely identified a high proportion of children with straight eyes and normal vision as having amblyopia.<sup>3</sup> Wright and colleagues attempted to improve on this test and designed the 10-prism diopter prism base down test which reduced the false positive rate of FPT, but over 25% of children with amblyopia tested normal.<sup>5</sup> Sener and coworkers tested 111 children with a mean age of 10.4 years and found good correlation between FPT and interocular acuity differences.<sup>6</sup> On the other hand Hakim found that FPT frequently identified fixation preference in children with strabismus, even though few of them had amblyopia,<sup>7</sup> reintroducing concerns that FPT does not accurately identify eyes with amblyopia.

The Baltimore Pediatric Eye Disease Study (BPEDS) is a study of ocular disorders in an urban population-based sample of non-Hispanic Whites and African American children 6 through 71 months of age. The visual acuity of both eyes of all children 30 months of age and older was tested both with standard visual acuity testing protocols and by fixation preference at the same visit. Herein we compare the results of those two commonly used tests of visual acuity in children.

### Methods

The Baltimore Pediatric Eye Disease Study (BPEDS) was designed to estimate and compare the prevalence of decreased visual acuity, strabismus, amblyopia, and refractive error in a population-based sample of African American and non-Hispanic White children 6 through 71 months of age living in Baltimore. A detailed description of study protocols is provided in a prior publication.<sup>8</sup> The protocol was approved by the Committee on Human Subjects Research at the Johns Hopkins Bloomberg School of Public Health as well as the Battelle Centers for Public Health Research and Evaluation Institutional Review Board (IRB) and the IRB of the Maryland Department of Health and Mental Hygiene. Parents and legal guardians completed each of these consents.

The study enrolled subjects from 54 contiguous census tracts in northeastern and eastern Baltimore City and adjacent portions of Baltimore County. Parents of all enrolled subjects were invited to bring their child to the study clinic for a detailed interview and ophthalmologic examination. The comprehensive eye examination included optotype visual acuity testing if possible, FPT, and other procedures described.<sup>8</sup> Fixation preference was assessed using a standardized protocol by a study-certified optometrist or ophthalmologist. If there was no tropia a 12 prism diopter base-down prism was used to dissociate the eyes. Fixation was graded on a four-point scale as "normal" if there was spontaneous alternation between the right and left

eyes or an apparent fixation preference reversed after switching the prism to the fellow eye. Fixation was graded as "likely normal" if fixation with the non-preferred eye was held for  $\geq 3$  seconds OR during smooth pursuit OR through a blink before refixation to the preferred eye. It was graded as "momentary" if fixation with the non-preferred eye was held for 1-3 seconds, and was graded as "no fixation" if refixation with the preferred eye occurred in < 1 second when the occluder was removed from the preferred eye. Patients with either momentary or no fixation were considered to have reduced vision in that eye.

Monocular single surrounded HOTV visual acuity was tested using the Electronic Visual Acuity (EVA) system and the Amblyopia Treatment Study (ATS) protocol.<sup>9, 10</sup> In brief this visual acuity testing protocol specifies a 3 meter test distance and includes a pretest to assess testability, a rapid screening phase to obtain an approximation of the acuity threshold, threshold testing, three larger letters to reengage the child, and a second threshold test.

To be eligible for this analysis the child had to be testable with both FPT and the ATS protocol using single-surrounded HOTV optotype testing in both eyes and had to be 30 through 71 months of age. Presenting visual acuity was used in all cases. Testing was done with spectacles worn for the 27 (1.9%) children who came to the clinic wearing glasses and for whom vision could be tested. A difference in visual acuity of two or more lines between the eyes was considered abnormal.

### Statistical Analysis

SAS Version 9.1.3 (SAS Institute, Cary, NC) was used for all statistical analyses. Optotype visual acuity was compared to fixation preference grade. Interocular differences on visual acuity testing were compared to findings from fixation preference testing using the chi-squared statistic. Confidence intervals (CI) for sensitivity and specificity were calculated using the normal approximation or the Poisson distribution where appropriate. All reported p-values are two-tailed.

### Results

A total 1,714 children 30 through 71 months of age were eligible for inclusion in this report, with 1435 (83.7%) testable by both FPT and ATS visual acuity protocol. Of these children 1,412 (98.4%) had "Normal" vision by FPT (Table 1), while 1,382 had less than two lines of interocular acuity difference (IOD). Fifty-three children had two or more lines of IOD in visual acuity. Of these, 7 had vision graded as "Momentary" or "No Fixation" (sensitivity =13.2% [95% CI = 5.3, 27.2]), while 46 had vision graded "Normal" or "Likely Normal" by FPT. In all 7 of the cases of poor FPT, the better-seeing eye was preferred. Low sensitivity and high specificity for detecting an IOD of two or more lines with FPT were seen for subgroups based on ethnicity; White children had 33.3% sensitivity (95% CI = 9.5, 57.2), and 99.6% specificity (95% CI = 98.7, 100) while African American children had 6.5% sensitivity (95% CI = 0.6, 23.2) and 99.3% specificity (95% CI = 98.3, 99.8, Table 2). For the entire study cohort, categorizing an FPT grade of "Momentary" or "No Fixation" as abnormal, FPT had a positive predictive value of 46.7% and a negative predictive value of 96.8% for an IOD of two or more lines.

Only 2 of 487 children 30 through 47 months of age were found with "Momentary" or "No Fixation" on FPT, and both of these children had one line or less IOD (Table 3), while all 13 children with IOD of two lines or more were identified as having "Normal" vision by FPT in this age range (0% sensitivity (0/13) [95% CI = 0, 28.5], 99.6% specificity [95% CI = 98.5, 100]). Performance was slightly better among children 48 through 71 months of age, with 7 of 40 children with two or more lines IOD found to have "Momentary" or "No Fixation" on FPT (sensitivity = 17.5% [95% CI = 7.0, 36.0], and specificity = 99.3% [95% CI = 98.5, 99.8],

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Table 3). When assessing FPT performance for 3 or more lines of IOD, only 5 of the 20 children (sensitivity = 25% [95% CI = 6.0, 44.0]) had FPT grades of "Momentary" or "No Fixation."

### Discussion

FPT is currently the clinical standard for testing vision in pre-verbal children.<sup>2</sup> Our study found that FPT, when used as part of a population-based research project, does not accurately identify preschool children with two or more lines of interocular difference in presenting visual acuity. Among those who were testable using both methods, many children who tested positive for a difference in visual performance between eyes by FPT were found to have no difference in visual acuity between the eyes, while a large majority with significant disparity in vision between the two eyes was categorized as normal by FPT.

While the positive predictive value of the FPT test was 47%, the vast majority of those with IOD of two or more lines were not identified with this test. FPT in the current study identified only 15% of preschool children who had an IOD of two lines or more on visual acuity testing and 25% of those with an IOD of three lines or more. The vast majority of children testable with single surrounded HOTV<sup>9</sup> and FPT were graded as "Normal" and therefore the sensitivity of FPT was low, although the specificity of the test was high. While these findings are discouraging, the very low proportion with grades of "Momentary" or "No Fixation" resulted in a positive predictive value for the test of 47% for two or more lines IOD. In addition the test performed poorly in children 31 to 47 months of age, failing to identify any of the 13 children with IOD of two lines or more. This result is worrisome to the clinician as this is the only widely available test for children unable to perform optotype acuity. Furthermore, these results call into question the use of FPT for clinical decision making. Given its poor performance, the accuracy of clinical interventions based on FPT is questionable as are studies that use FPT as an outcome measure.

Our study has several important advantages. We trained and standardized our testers and evaluated both the testers and procedures on an ongoing basis. In addition all results were prospectively gathered, with the FPT tester masked to the visual acuity. However, our study has several limitations. Only 64% of enrolled children participated in the clinical evaluation, but they were similar to the general population of children in nearly all respects (data published elsewhere).<sup>8</sup> There is little reason to believe that the response to the visual acuity testing procedures would be different if the entire population had been studied. A substantial portion of children were unable to be tested in both eyes with optotype testing, and several of these had grades of "Momentary" or "No Fixation" on FPT. If all of seven of the children with FPT testing of "Momentary" or "No" fixation who were missing visual acuity data did indeed have an IOD of two or more lines, the sensitivity of FPT would only have increased to 23%, indicating that the inability to test younger children did not unduly influence the results.

There is an important limitation to our study of FPT and acuity. There were few subjects diagnosed with strabismus in this prevalence study so it is not possible to determine if FPT is useful for ongoing management of strabismic children. In addition the small number of strabismic patients makes it difficult to compare our findings to previously published work on FPT, which often is used for the testing of strabismic amblyopia. Sener and coworkers found reasonable correlation between IOD and FPT, but he was testing older children.<sup>6</sup> Hakim found that 75% of strabismic children tested positive by FPT, but only 13% had an IOD of two lines or more.<sup>7</sup> The author correctly noted that using the results of FPT could often lead to unnecessary treatment.

In summary FPT does not accurately detect the presence or absence of visual acuity differences between eyes in non-strabismic patients when used by experienced and trained licensed eye

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care professionals. Thus, the clinical value of this test was poor in our study; if our experience can be generalized, its use for diagnosis and monitoring interventions should be reconsidered.

### Acknowledgements

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# Table 1 Fixation Preference Testing and Inter-Ocular Difference in Vision for All Children Age 30–71 Months

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$ \begin{array}{cccccccccccccccccccccccccccccccccccc$		Normal		Aauon 11 tetet enec 1 testing Categor		Total
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	IOD Level					
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	0-1 lines	1367 (98.9)	7 (0.5)	5 (0.4)	3 (0.2)	1382 (100)
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	2 lines	31 (93.9)	0	2 (6.1)	0	33 (100)
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\geq 3$ lines	14 (70.0)	1(5.0)	1(5.0)	4 (20.0)	20 (100)
243 4 2 5	Total	1412 (98.4)	8 (0.6)	8 (0.6)	7(0.5)	1435 (100.0)
	Missing VA in at least one eye	243	4	5	2	279
	IOD = Inter-ocular difference,	, $VA = visual acuity$				
IOD = Inter-ocular difference, VA = visual acuity						

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 $\overset{*}{25}$  of these are missing both fixation preference testing and visual acuity

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IOD Level	W Nor	Normal AA	Likely Normal W	A	Mome W	Momentary	W No Fixation	cation AA	W To	Total AA
0-1 lines	549 (99.1)	684 (98.7)	3 (0.5)	4 (0.6)	2 (0.4)	2 (0.3)	0	3 (0.4)	554 (100)	693 (100)
2 lines	5 (83.3)	21 (95.5)	0	0	1(16.7)	1(4.6)	0	0	6 (100)	22 (100)
$\geq 3$ lines	5 (55.6)	7 (77.8)	0	1 (11.1)	1(11.1)	) 0	3 (33.3)	1 (11.1)	9 (100)	9 (100)
Total	559 (98.2)	712 (98.3)	3 (0.5)	5(0.7)	4 (0.7)	3 (0.4)	3 (33.3)	4 (0.6)	569 (100.0)	724 (100.0)
Missing VA in at least one eye	<u>81</u>	139	5	, I	Ţ	Ţ	, Ċ	, I	104*	149**

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AA = African-American

IOD = Interocular acuity difference

VA = visual acuity

 $\overset{*}{_{\rm I7}}$  are missing both fixation preference testing and visual acuity

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 Table 3
 Fixation Preference Testing and Inter-Ocular Difference for All Children Age 30–71 Months

					Manutana -			and the second se	Ē	Total
[OD Level	30-47 <sup>#</sup> Normal	nal 48-71	Likely Normal 30–47	ormal 48-71	101000 30-47	Momentary 30–47	30-47 48-71	48-71	30-47	48-71
	174 (99.4)	893 (98.7)	1 (0.2)	6 (0.7)	2 (0.4)	3 (0.3)	0	3 (0.3)	477 (100)	905 (100)
	9 (100.0)	22 (91.7)	0	, O	0	2(8.3)	0	0	9 (100)	24 (100)
	4(100.0)	10(62.5)	0	1 (6.3)	0	1(6.3)	0	4 (6.3)	4(100)	16 (100)
	187 (99.4)	925 (97.9)	1 (0.2)	7 (0.7)	2 (0.4)	6(0.6)	0	7 (0.7)	490(100.0)	945 (100.0)
Missing VA in at least one eye	220	23	4	0	5	0	7	ŝ	249*	30**

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IOD = Interocular acuity difference, VA = visual acuity

\* 21 are missing both fixation preference testing and visual acuity

\*\* 4 missing both fixation preference testing and visual acuity