The Amblyopia Treatment Study Visual Acuity Testing Protocol

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Objective: To evaluate the reliability of a new visual acuity testing protocol for children using isolated surrounded HOTV optotypes.

Methods: After initial pilot testing and modification, the protocol was evaluated using the Baylor-Video Acuity Tester (BVAT) to present isolated surrounded HOTV optotypes. At 6 sites, the protocol was evaluated for testability in 178 children aged 2 to 7 years and for reliability in a subset of 88 children. Twenty-eight percent of the 178 children were classified as having amblyopia.

Results: Using the modified protocol, testability ranged from 24% in 2-year-olds to 96% in 5- to 7-year-olds. Test-retest reliability was high ($r=0.82$), with 93% of retest scores within 0.1 logMAR unit of the initial test score. The 95% confidence interval for an acuity score was calculated to be the score ±0.125 logMAR unit. For a change between 2 acuity scores, the 95% confidence interval was the difference ±0.18 logMAR unit.

Conclusions: The visual acuity protocol had a high level of testability in 3- to 7-year-olds and excellent test-retest reliability. The protocol has been incorporated into the multicenter Amblyopia Treatment Study and has wide potential application for standardizing visual acuity testing in children.

MATERIALS AND METHODS

CONCEPTUAL DEVELOPMENT OF THE VISUAL ACUITY TESTING PROTOCOL

The visual acuity testing protocol was developed with the following aims: (1) to present HOTV optotypes in a logMAR progression; (2) to present optotypes in a “crowded” manner, which would increase the test’s sensitivity for amblyopia; (3) to be able to test developmentally normal children aged 3 to 6 years; (4) to be able to easily train technicians at multiple sites to administer the test; and (5) to be able to conduct the testing using equipment already available in many pediatric eye practitioners’ offices.

The protocol initially was developed to test visual acuity in the range of 20/125 to 20/15 using the 4-letter set “H,” “O,” “T,” and “V.” These optotypes were displayed as single-letter presentations with surround bars of the same stroke width at a distance of half the optotype height from the optotype (Figure 1). The BVAT consists of a monitor placed and calibrated at a test distance of 10 to 20 ft (3.6 m) from the subject, which is controlled by a hand piece held by the operator positioned at the subject’s side. Single surrounded letters from 20/125 to 20/15 can be presented in random order in a sequence that approximates a logMAR progression if the 20/70 letter size is skipped. A matching card is used for younger children to facilitate their response, and it is often helpful even in older children. A letter size is referred to as a logMAR level throughout the manuscript. The progression from 20/15 to 20/125 (skipping 20/70) approximates to 0.1 logMAR unit steps. The term “line” is not used to avoid potential confusion because these protocols used isolated surrounded optotypes.

The testing protocol consists of a pretest to assess testability, followed by a rapid screen to obtain an approximation of the acuity threshold, and then threshold testing. Single surrounded optotypes are used for the entire protocol. For a child being tested for the first time, a pretest, consisting of 20/125 size letters viewed binocularly, is used to determine whether the child can potentially perform the test. If a child correctly identifies 4 of 4 or 5 of 6 letters, the child is tested monocularly using an occlusive patch over the fellow eye. The right eye is tested first. The first step of the monocular testing is designed to provide an approximate estimate of threshold (called “screening”). A single optotype of each size is presented, starting at 20/100. When a letter is failed, threshold testing (“phase 1”) begins 2 logMAR levels above the level failed in screening; for most children, this would be above threshold. For threshold testing, a level is considered “passed” when 3 of 3 or 4 of 4 letters are correctly identified or “failed” when 2 letters are missed at a given level. The probability of correctly guessing 3 of 4 HOTV letters is about 5% and of correctly guessing 3 of 4 at 2 consecutive levels is less than 1%. Single surrounded letters of the same size are shown until the child either passes or fails the logMAR level. If the initial level is passed, then the next smallest logMAR level is tested in a similar fashion, and the test continues until a level is failed or 20/15 is passed. If the initial level is failed, then the next largest logMAR level is tested in a similar fashion and so forth until a level is passed. In our original pilot protocol, this was the end of the test, and visual acuity was considered to be the smallest level that was passed.

EXTENSION OF THE VISUAL ACUITY TESTING PROTOCOL TO LOW VISION

The original protocol, developed for measuring acuity of 20/125 or better, was extended to test acuity as low as 20/400. For the adaptation of the protocol for testing of 20/160 to 20/400 on the BVAT, it is necessary to reduce the testing distance. At the standard 10- to 20-ft working distance, the 20/125 optotype is the largest size for which surround bars can be presented. For measuring visual acuity less than 20/125, a distance of one fourth the standard distance was chosen (eg, 2.5 ft [0.75 m] in a 10-ft [3-m] lane). At this distance, presenting optotypes from 20/100 to 20/40 (omitting 20/70) becomes an approximate logMAR progression from 20/400 to 20/160.

INITIAL PILOT TESTING

Initial pilot testing of the acuity protocol using the BVAT was conducted on 285 children at 5 study sites in the United States. All participating sites obtained institutional review board approval for the testing protocol and procedures. After informed consent was obtained, 2 separate tests of visual acuity were performed by independent examiners at the same office visit using the methods described in the “Testing of the Modified Protocol” subsection. Children were aged 24 to 93 months; 13% were considered to have developmental delay by parental report. Forty-two percent were classified as having amblyopia or another cause of reduced visual acuity.

Most children aged 3 years or older could be successfully tested using this protocol: 22% (10/45) of the 2-year-olds (visual acuity measured in each eye on the first examination), 66% (33/50) of the 3-year-olds, 88% (65/74) of the 4-year-olds, and 98% (114/116) of the 5- to 7-year-olds. The ages of the 180 children used for reliability analysis ranged from 2 to 7 years (mean±SD, 5.2±1.3 years).

Test-retest results indicated lower than desirable reliability; 10% of children scored more than 1 logMAR level (0.1 logMAR unit) different on the retest, and the Pearson correlation coefficient was 0.77. Of greatest concern was the finding that 9% of retests had a score 2 or more logMAR levels (≥0.2 logMAR unit) better than the first test, suggesting that inattention could have been a factor in the first test. In some cases, it was also our clinical impression that loss of the child’s attention resulted in a performance worse than the child’s true acuity. These issues led us to modify the visual acuity testing protocol.
MODIFICATION OF THE VISUAL ACUITY TESTING PROTOCOL

The acuity protocol was modified to refine the estimate of threshold by adding a “reinforcement phase,” followed by a second testing for threshold. Analogous to part of a “staircase” procedure, and applying methods developed for clinical Teller acuity card testing,21 larger optotypes are presented to “get the child back on track” or “on a roll.” Reinforcement consists of presenting 3 optotypes of descending size, starting 3 levels above the level failed in phase 1. At the discretion of the tester, the reinforcement phase could be repeated after a break of a few minutes (this was rarely used, and after completion of the present study it was omitted from the protocol). The responses from the reinforcement phase do not contribute to the visual acuity score. Regardless of whether the responses in the reinforcement phase are correct, the last logMAR level failed in phase 1 is retested by the same procedure used in phase 1 (called “phase 2”). If this level is again failed, the test is stopped. If the level is passed, the test continues with smaller levels until a level is failed. The final visual acuity is defined as the smallest level passed in phase 1 or phase 2. The entire testing protocol is given in Table 1, and the scoring sheet is shown in Figure 2.

TESTING OF THE MODIFIED PROTOCOL

After informed consent was obtained, the modified protocol was used to test acuity in 178 children at 6 sites. One primary site contributed 92 children (52%) and the remaining 5 secondary sites contributed 86 children (48%; range, 9-26 children per site). Each BVAT was calibrated before the study according to the manufacturer’s instructions. An Internet-based program, simulating the testing protocol on the BVAT, aided the training of the visual acuity testers. Children aged 2 to 7 years were recruited without regard to diagnosis. Children with developmental delay were included so that the assessment of testability would reflect the population of patients who present to pediatric eye disease practices. Developmental delay was assessed by simply asking the parent whether the primary caregiver had identified developmental delay. No attempt was made to formally evaluate the degree of developmental delay. At the conclusion of the office visit, each child’s clinical diagnosis was recorded by the treating physician or by a tester in communication with the treating physician.

Each child underwent acuity testing of the right eye first and then the left eye using the described protocol on the BVAT. A child was considered to be “testable” when the protocol could be completed for both the right and left eyes on the first examination. Testable children were then retested by a separate examiner who was unaware of the results of the first test. The second test was typically performed within 5 to 15 minutes of the first test and always during the same office visit. No attempt was made to randomize, or otherwise determine, the tester order at each site.

Frequently, no specific presentation protocol was used. Even when a protocol for linear presentation of HOTV optotypes was adopted,20 younger children were sometimes confused by lines of optotypes, providing a rationale for the common clinical practice of using single optotypes.

Data from all 178 children were used in the testability analysis. However, only data from the 88 children who completed testing of both eyes twice, without tester errors in both examinations, were used in the test-retest reliability analysis. For testable children, each visual acuity test scoring sheet was evaluated to determine whether tester errors had been made that would affect the acuity score. Tester errors occurred more often at the secondary sites (48% of children) than at the primary site (8% of children). Tester errors did not affect the assessment of testability because completion of the test for each eye did not depend on whether the testing protocol was followed precisely. When present, errors were usually due to unfamiliarity with the protocol early in the implementation process. This prompted additional training of the testers, which reduced the frequency of errors. Data from the children tested at the shorter testing distance for optotype sizes larger than 20/125 were included in the testability analysis but not in the test-retest reliability analysis because reliability might vary according to testing distance. Such differences in reliability between testing distances would be expected because of differences in attention and greater potential errors in estimating visual acuity induced by subject movement toward and away from the screen at the shorter distance.

STATISTICAL METHODS

Testability was evaluated for each age year in a frequency distribution. The association of age-adjusted testability with developmental delay, ocular diagnosis, and performance site was assessed using the Cochran-Mantel-Haenszel statistic.

For the test-retest reliability analysis, visual acuity data were converted to logMAR equivalents. Right and left eye data were combined for analysis after determining that results were similar for separate eye-specific analyses (combining eyes is a valid method of analysis provided that statistical tests adjust for the decreased variance produced by the intereye correlation). Frequency distributions of the differences in visual acuity scores between the first and second test in each eye were constructed and Pearson correlation coefficients were computed overall, and in subgroups, based on diagnosis, visual acuity, age, site, and whether the child had previous experience with HOTV testing. Similar analyses were conducted for interocular difference (IOD) data. Statistical comparisons of proportions were made using a χ² test adjusted for the intereye correlation.23 The SE of measurement for the test was computed separately for each eye and then averaged for reporting and establishing a 95% confidence interval (CI) for an acuity score.24 A 95% CI for a change in an acuity score from a baseline value was computed by 2 methods: one based on the SE of measurement from the first test and one based on the SD of the test-retest differences. These were calculated separately for right and left eyes and then averaged. The CI for the IOD was based on the SD of the test-retest difference in IOD.

Statistical analyses were performed using statistical software (SAS PC version 8.01; SAS Institute Inc, Cary, NC).
The purpose of the present study was to develop and refine a visual acuity testing protocol for isolated surrounded HOTV optotypes.

Figure 1. The appearance of a single surrounded HOTV letter.

Table 1. Instructions for Visual Acuity Testing Protocol

*If the patient will not give a response for a letter, encourage him or her to guess. Be sure to mark an “X” to indicate letters that were shown for which the patient would give no response. Specific instructions for using the protocol with a Baylor-Video Acuity Tester (BVAT): 20/70 letter size is not part of logMAR progression and is skipped; because the largest surrounded HOTV optotype is 20/125 when calibrated for a 10- to 20-ft (3-6 m) distance, the testing distance must be reduced to one-fourth for testing of acuity from 20/160 to 20/400.

**If the last level tested in phase 1 is passed, the reinforcement phase can be skipped at the tester’s discretion.
The 88 children included in the test-retest reliability analysis had a mean ± SD age of 5.3 ± 1.1 years. Twenty-five children were classified as having amblyopia, and an additional 4 had other causes for reduced visual acuity (Table 2). Visual acuity on the initial test, combining right and left eye data, ranged from 20/15 to 20/80, and 79% were 20/30 or better (Figure 4). The IOD in logMAR levels (0.1 logMAR unit) on the initial test was 0 in 36 children (41%), 1 in 31 (35%), 2 in 11 (13%), and 3 or more in 10 (11%).

The correlation between initial and retest visual acuity scores was 0.82. In 93% of the 176 eyes, the retest score was within 0.1 logMAR unit of the initial test score. The IOD test-retest correlation was 0.75. The retest IOD was within 1 logMAR level (0.1 logMAR unit) of the initial IOD in 75 children (85%) (Figure 5). The 95% CI for the IOD was calculated to be the IOD ±0.15 logMAR unit and for a change in IOD to be the difference ±0.21 logMAR unit.

There were no meaningful differences in the results when the data were analyzed separately for right and left eyes (test-retest correlations: 0.84 and 0.81, respectively; test-retest scores within 0.1 logMAR unit: 93% and 92%, respectively; and SE of measurement: 0.060 and 0.067, respectively). There were also no differences when the data were analyzed by subgroups based on site, diagnosis, age, and whether the child had previous experience with HOTV testing (data not shown).

For the final visual acuity protocol, the percentage of test-retest acuity scores differing by 2 or more logMAR levels (≥0.2 logMAR unit) was lower than the percentage using the original protocol (7% vs 16%; P = .01).

**COMMENT**

We have described a structured protocol for measuring visual acuity using isolated surrounded HOTV optotypes in children aged 2 to 7 years. After finding that our original protocol had a lower than desirable test-retest reliability, we added the testing of additional optotypes around threshold to further refine its estimate. With our final protocol, testability was high for children aged 4 years or older, moderate for those aged 3 years, and low for those aged 2 years. Test-retest reliability was excellent, with 93% of retests within 0.1 logMAR unit of the initial test score.
In the clinical management of children with amblyopia, considerable weight is given by many clinicians to the IOD. In our study, the test-retest reliability of the IOD was no better than the reliability of the visual acuity measurements themselves, and perhaps less so.

Although we initially had a high rate of tester error in administering the visual acuity protocol, most of these errors occurred at secondary sites by inexperienced testers. This indicated the need to modify the instructions to the testers, which led to fewer tester errors as the study progressed. Our experience in the ongoing Amblyopia Treatment Study, in which the acuity protocol is being used at 52 sites recruiting 400 children, is that with simple instruction, testers learn to follow the protocol quickly, and errors affecting the visual acuity score are few. Ongoing experience with the visual acuity protocol, in our clinical practices, also confirms that the protocol is not too difficult to teach, learn, and implement.

Using a separate tester for the retest added a second source of potential variability such that the variability due to the child and that due to the tester cannot be separated. However, in designing the study we believed that this was outweighed by the value of having the second tester masked to the result of the first test. It seemed probable that most of the variability is related to the child’s performance rather than to the tester.

### Table 2. Characteristics of Children in the Testability and Reliability Analyses*

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Children Included in Testability Analysis (n = 178)</th>
<th>Children Included in Reliability Analysis (n = 88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y</td>
<td>4.8 ± 1.4</td>
<td>5.3 ± 1.1</td>
</tr>
<tr>
<td>Age, y</td>
<td>25 (14)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>3</td>
<td>21 (12)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>4</td>
<td>60 (34)</td>
<td>33 (38)</td>
</tr>
<tr>
<td>5</td>
<td>32 (18)</td>
<td>19 (22)</td>
</tr>
<tr>
<td>6</td>
<td>31 (17)</td>
<td>23 (26)</td>
</tr>
<tr>
<td>7</td>
<td>9 (5)</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Boys</td>
<td>77 (43)</td>
<td>36 (41)</td>
</tr>
<tr>
<td>Ethnicity</td>
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<tr>
<td>White</td>
<td>147 (83)</td>
<td>74 (84)</td>
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<tr>
<td>Black</td>
<td>17 (10)</td>
<td>8 (9)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (2)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2)</td>
<td>1 (1)</td>
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<tr>
<td>American Indian</td>
<td>2 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (3)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Developmental delay</td>
<td>20 (11)</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Clinical diagnosis</td>
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<td></td>
</tr>
<tr>
<td>Normal</td>
<td>117 (66)</td>
<td>59 (67)</td>
</tr>
<tr>
<td>Amblyopia</td>
<td>49 (28)</td>
<td>25 (28)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (7)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Previously tested with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>isolated surrounded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOTV letters†</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Data are given as number (percentage) of children except where indicated otherwise.
†Child had a previous visual acuity test using isolated surrounded HOTV letters but not necessarily this protocol.

**Figure 3.** Percentage of children who could be tested using the final protocol according to age.

**Figure 4.** Distribution of visual acuity scores on the initial examination using the final protocol in 176 eyes of 88 children.

**Figure 5.** Distribution of test-retest differences in acuity scores using the final protocol in 176 eyes of 88 children. A positive value indicates that the acuity score was better on the retest than on the initial test and vice versa.
Our addition of a second attempt at “the level failed” on the initial threshold testing increases the probability that a child will have an acuity score better than threshold strictly by guessing. The probability of achieving a score 1 logMAR level (0.1 logMAR unit) better than threshold by guessing could be as high as 9.9%, but the probability of achieving a score 2 or more logMAR levels (0.2 logMAR unit) better than threshold by guessing is less than 1%. However, the exact probabilities under testing conditions cannot be calculated because they are conditional on whether the acuity threshold is reached during testing and depend on where between 2 logMAR levels true acuity lies and the shape of the psychometric function. This increase in the probability of having an acuity score 1 logMAR level (0.1 logMAR unit) better than threshold by guessing, with the addition of phase 2, is outweighed by a reduction in the likelihood that the acuity is underestimated because of errors made by the child owing to inattention. Future work is needed to define the shape of the psychometric functions obtained from preschool children using this protocol.

Whereas our protocol is designed for testing acuity of 20/400 to 20/15, our test-retest reliability analysis was principally conducted on eyes with visual acuity of 20/30 or better. In addition, most of our children had no ocular cause for decreased acuity and were aged 4 to 7 years. Nevertheless, neither the data from this study nor our ongoing clinical experience using this protocol on a daily basis suggest that the reliability varies according to age, diagnosis, or level of acuity. Further reliability testing would be needed to formally establish this. We assessed the testability of the low-vision protocol for optotype sizes less than 20/125 in only 6 children.

Our acuity protocol compares favorably with other published methods of measuring visual acuity in children in terms of testability and reliability. Although we are unaware of studies that report testability for isolated surrounded HOTV optotypes, Friendly13 and Kastenbaum et al25 described a pattern of increasing testability by age similar to our results for isolated unsurrounded HOTV optotypes. Friendly13 described 15 (88%) of 17 children younger than 3 years as testable, whereas Kastenbaum et al25 described none of 17 children younger than 41 months as testable. Testability approached 100% after age 31⁄2 years in the study by Friendly and after 5 years for Kastenbaum et al. In a study of line HOTV presentation, for 167 children aged 3 to 5 years, Sprague et al20 found that testability ranged from 84% in 3-year-olds to 97% in 5-year-olds. However, 22% of 3-year-olds and 17% of 5-year-olds needed “isolation” of the letters to complete testing. In a study of 105 children aged 2 to 7 years using surrounded “C” and “O” optotypes, Fern and Manny2 found a similar “testability by age” profile to ours, with testability ranging from 30% in 2-year-olds to 100% in those 5 years and older. Regarding reliability, Harvey et al3 tested line HOTV acuity in 36 children aged 3½ years and 48 aged 4½ years as part of the multicenter Cryotherapy for Retinopathy of Prematurity (CRYO-ROP) study. They reported test-retest rank correlation coefficients of 0.81 and 0.85, respectively, with 40% and 33%, respectively, of retests having exact agreement and approximately 90% within 1 octave (0.3 logMAR unit). For ETDRS testing of 44 children aged 5½ years, Harvey et al3 found approximately 30% exact agreement and 90% within 1 line (1 logMAR level, ie, 0.1 logMAR unit). Although Sprague et al20 reported test-retest reliability for HOTV testing in 3- to 5-year-olds, the results were scored by letter, and he discarded the data from the first one third of the children, so the studies are not comparable. McGraw et al26 studied 68 visually normal children (mean ± SD age, 5.32 ± 1.15 years) using the Glasgow acuity cards incorporating 6 letters (XVOHUY) in lines of 4 surrounded by a crowding box. They found 95% of retests to be within 1 logMAR level (0.1 logMAR unit). Studies of adults using the ETDRS chart show simi-
lar results; Elliott and Sheridan27 studied 29 patients with cataract and found that 95% of retinal visual acuity scores differed by no more than 0.1 logMAR unit.

We believe that our final protocol is a reasonable compromise between testability and precision for acuity testing of children, using current technology in the pre-school age range, in usual office practice and in multicenter clinical trials. Increasing the total number of letter presentations would be problematic in the testing of many young children due to their limited attention span. Under ideal circumstances, given a great deal of time for each patient and excellent patient cooperation and attention, a formal staircase procedure or similar type of testing strategy might be used to estimate the visual acuity threshold, with several reversals around the estimated threshold.28 Alternatively, acuity could be measured by testing multiple optotypes at every logMAR level, similar to the ETDRS protocol.2 Such strategies might address a weakness of our current protocol, that of measuring visual acuity when the response on a single letter determines whether the acuity is assigned as 1 logMAR level or the next.

We are currently developing a PC version of our acuity protocol to present HOTV optotypes in a logMAR progression from 20/400 to 20/16. This will eliminate the difficulties in using the BVAT at 2 test distances to measure acuity lower than 20/125 with surrounded HOTV optotypes. It will also reduce the training necessary for testers in the implementation of the protocol and minimize tester errors. We are also developing an alternative PC-based testing strategy using a modified binary search.
approach\textsuperscript{29} that holds promise for increasing precision and providing a measure of variability of the point estimate of visual acuity threshold without reducing testability. The PC approach will also readily permit use of different character sets, which can be selected based on the child's age and development. Incorporating more than 4 letters will reduce the probability of passing a level by chance, although this must be balanced against the possibility that it will reduce the testability of younger children. Adding even just 1 letter so that there are 5 possibilities (eg, HOTVX) substantially reduces the chance probability of passing a logMAR level. In summary, we developed a new visual acuity testing protocol for isolated surrounded HOTV optotype presentations. The protocol shows good testability in 3- to 7-year-olds and has excellent test-retest reliability. Although we recognize that some of the older children might perform ETDRS testing, maintaining the same testing method is important in a multicenter, longitudinal study because visual acuity test performance can vary according to the nature of the optotype presented. Our acuity protocol provides standardized visual acuity testing in children and has been incorporated into the ongoing Amblyopia Treatment Study.

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