

Development and Validation of a New Method for Visual Acuity Assessment on Tablet in Pediatric Population: eMOVA Test

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Abstract

Background Amblyopia is a major public health problem. Its screening and management require reliable methods of assessing visual acuity. Many tests are available, some of which are used as a reference and the advent of new technologies sees many others whose validity is not proven. The objective of our study was to develop a tablet-based visual acuity test adapted to the pediatric population: the eMOVA test (electronic Measurement Of Visual Acuity).

Methods We did a study comparing the eMOVA test with the Rossano-Weiss test. All children aged 3 to 8 attending the ophthalmic and pediatric consultation between September 2016 and June 2017 were included. The results in terms of visual acuity were compared as well as the duration of each test, its comprehension, its acceptability and the attention of the child during the test.

Results The eMOVA test overestimated visual acuity by 0.06 logMAR. This difference, statistically significant, was not clinically relevant. The duration of the eMOVA test was longer than the reference test, but it was less painful and more appreciated by children and their parents.

Conclusion The e-MOVA test appears as a reliable method of assessing visual acuity that could be used both in consultation and on a larger scale in the context of screening as well as for the care of the most difficult children.

Background

Amblyopia and refractive abnormalities are the two leading causes of preventable visual impairment in children. Arnold et al. have shown that one in 40 preschool children have amblyopia with visual acuity less than 20/40 and that one in five children has a risk factor for amblyopia (1).

Most causes of amblyopia are treatable, provided they have been detected early enough.

Indeed, there is a so-called "sensitive" period during which the maturation of the visual pathways of the child is not completed. Proper management of amblyopia before the end of this period can completely or partially reverse it. The taking charge will be etiological at first with sometimes the need for surgery. In a second step, a measurement of the refraction under cycloplegia will allow the wearing of the adapted optical correction. Then, a reeducation of amblyopia can be started with optical penalization. (1) Effective screening for these disorders is therefore necessary and should be sought as early as possible. This screening, which is a public health priority, requires assessment methods adapted to the child and the disorders sought, ranging from mass screening to pediatric ophthalmology consultation.

The methods of assessing the visual acuity of the child are numerous and varied. None meet the characteristics of an ideal test, defined as follow angular acuity, logarithmic progression scale, space between optotypes = size of optotype, space between lines = size of optotype, sufficient and odd number

of optotypes (five), confusion's letter at the beginning and the end, luminance 150 – 650 cd/m², Contrast > 70 % (2–4).

The growing demand for new technologies in the medical field is pushing us to evolve. In 2011, WHO defined the term "mHealth" as a medical and public health practice supported by mobile devices such as mobile phones, patient monitors, PDAs, and other wireless devices(5). In ophthalmology, digital applications have developed with diabetes (6) and AMD (7), with the development of adapters for photographs of the anterior and posterior segments (8), the study of contrast sensitivity and color vision (9,10). Because of their portability, these new technologies are particularly interesting for improving eye health in developing countries (11). In the field of pediatric ophthalmology, some authors have proposed a binocular approach to amblyopia with rehabilitation exercises in the form of games on iPad with encouraging results(12–16). The new technologies are constantly improving and could allow us to overcome these technical difficulties. In addition, their growing appeal to the pediatric population makes it a real advantage. The objective of our study was to develop a tablet application that reliably assesses children's visual acuity in order to provide an effective tool for screening visual disorders.

Methods

- eMOVA test and gold standard

We have developed a visual acuity test on tablet: eMOVA test (electronic Measurement Of Visual Acuity) developed in near vision in a first version. We developed a method by pairing with Raskin's E (Figure 1). This choice was motivated by the desire to be able to use the same optotype with the eMOVA test and the Rossano-Weiss test. In our current practice, the Rossano-Weiss test is widely used to assess the visual acuity of children. Drawings are used for preverbal children, then numbers and Raskin's E when it is possible. It is preferable to use a method of assessing visual acuity based on the minimum resolution angle and the Raskin's E allows that. It was necessary to look for correspondences in sizes between the optotypes of the two tests. The size of the tablet optotypes depends on the size of a pixel. We have developed a sequence on tablet that was as close as possible to that purposed with our reference test with the best size match.

- Distance of realization of the test

We kept a distance of 40 cm between the eyes of the child and the screen of the tablet. Since accommodation is dependent on reading distance, it is very important to adopt a fixed distance when assessing near visual acuity. The American Academy of Ophthalmology recommends a distance of 35 to 40 cm for assessing visual acuity. When a child watches a test at a distance he chooses himself (between 5 and 20 cm), the visual acuity measured decreases by 0.15 logMAR compared to the visual acuity measured at 40 cm. At 40 cm, the influence of accommodation is minimal. This distance makes it easier to compare near and far visual acuity measurements. There is no evidence for a near and far difference in visual acuity in children with normal or reduced vision when the distance of 40 cm is

respected. From the age of 4, children are very good at keeping this distance when measuring near vision (17).

- Study design

We carried out a single-centric study comparing the evaluation of visual acuity by the eMOVA test against the Rossano-Weiss reference test. Both tests were conducted blindly by two different stakeholders during the same consultation under the same environmental conditions. The tests were administered by one ophthalmologist and three orthoptists trained in the two tests. The patients were divided equally between each practitioner and randomly according to the order of arrival in consultation. The first test to be presented to the child was randomly selected according to the order of arrival in consultation. The child stayed installed and the practitioner changed for the second test. A sequence effect was sought to verify the absence of bias linked to the order of presentation because concentration and fatigability are important factors in pediatric clinics. The right eye was the first eye tested for all children. The inclusion criteria were: - Child aged 3 to 8 years - Child able to express his agreement to the tests and parent or legal representative who has given his consent. The exclusion criteria were: - Patients who have already performed the eMOVA test once - Patients with a disability suggesting that subjective assessment of visual acuity is not possible. The primary endpoint was the measurement of visual acuity presented in log and decimal notation. The secondary endpoints were: - The understanding of the test - The child's attention when carrying out the test - The respect of the distance of realization of the test - The duration of the test - The child's discomfort during the test. The understanding of the test and the child's attention were subjectively evaluated from 0 to 5 by the examiner, corresponding to a very bad, bad, average, good, very good understanding or attention. The distance was checked using a measurer and the examiner gave a score from 1 to 5 according to the same methods as for the previous criteria. The duration of the test was measured using a stopwatch and the difficulty of the test was assessed using the FLACC scale (Face Legs Activity Cry Consolability) (18–20). The duration of use of a tablet or smartphone by the child at home and the number of previous consultations were also collected. The study and data collection conformed to all local laws and were compliant with the principles of the Declaration of Helsinki. Local institutional review board approved our study.

- Statistical analysis

The analysis of the results was carried out in several stages. First, we calculated the average visual acuity obtained with each of the two tests as well as the average difference in visual acuity obtained between the two tests for each patient. In a second step, to test the equivalence of the two visual acuity tests, we carried out a concordance study for the analysis of the main judgment criterion. The concordance analysis for the quantitative variables were performed graphically using the Bland & Altman method and calculating the intra-class correlation coefficient (ICC). For qualitative variables, the concordance was evaluated by calculating the Kappa coefficient. The 95% confidence intervals of these two indicators were calculated using a bootstrap resampling method. Third, a superiority study was conducted for the analysis of secondary endpoints. She compared the quantitative variables using the Wilcoxon signed

rank test and the qualitative variables using the Bhapkar test. A sequence effect was tested by comparing visual acuity according to the sequence of realization using a signed rank test of Wilcoxon in order to know if the performances found with one test were influenced by the previous realization of the other test. A p-value <0.05 was considered statistically significant. The analysis were performed using R version 3.2.2 software.

Results

- Patients characteristics

Criteria collected	Number
Age : (in months)	
- Between 36 and 59	28 % (27/96)
- Between 60 and 66	22 % (21/96)
- Between 67 and 79	23 % (22/96)
- Between 80 and 112	24 % (23/96)
Sex :	
- Girls	56 % (54/96)
- Boys	44 % (42/96)
Number of previous consultations préalables	
- First consultation	16 % (15/96)
- Between 1 and 5	38 % (36/96)
- Between 6 and 10	21 % (20/96)
- > 10	25 % (24/96)
Reason for consultation	
- Screening	25 % (24/96)
- Amblyopia or known risk factor of amblyopia	75 % (72/96)
Diagnosis :	

Known amblyopia	12 % (12/96)
Strabismus	34 % (33/96)
Hypermétropia	22 % (21/96)
Astigmatism	10 % (10/96)
Myopia	4 % (4/96)
Duration of use of a smartphone or tablet at home per week	
- < 3 hours	62 % (60/96)
- between 3 and 7 hours	22 % (21/96)
- between 7 and 14 hours	13 % (12/96)
- > 14 hours	3 % (3/96)

Table 1. Patients characteristics

One hundred patients were included between September 2016 and June 2017. The average age was 68 months. Four children were excluded from the analysis because they could not perform the tests. The characteristics of the 96 patients included are presented in Table 1. Amblyopia was defined as a monocular acuity less than or equal to 6/10 or with a difference in visual acuity greater than or equal to 2/10 between the two eyes. Children with uni or bilateral amblyopia were included as amblyopic. Any absence of emmetropia was recorded as myopia, hyperopia or astigmatism.

- Main outcome (Table 2)

The average visual acuity obtained with the Rossano-Weiss test was -0.22 logMAR or 6.2/10 for the right eye and -0.24 logMAR or 6.1/10 for the left eye. The mean visual acuity

obtained with the eMOVA test was -0.28 logMAR or 5.9/10 for the right eye and -0.24 logMAR or 6.1/10 for the left eye. The mean difference in visual acuity between the two groups was -0.06 logMAR or 0.3/10 for the right eye and 0.00 logMAR or 0/10 for the left eye. The maximum visual acuity obtained was -0.18 logMAR for both tests. The minimum visual acuity achieved was -0.67 logMAR and -1.2 logMAR, respectively, for the Rossano-Weiss test and the eMOVA test. The first quartile, median, third quartile and mode were -0.18 logMAR for all groups. Overall, the differences in visual acuity measured by the two tests are very limited. In order to test the equivalence of the two tests, a statistical analysis of concordance was conducted. For this analysis, we studied two sets of values to verify the validity of our results: the first on the right eye and the second on the left eye of each patient. The correlation coefficient r , of the visual acuity measurement with the Rossano-Weiss test and the eMOVA test was 0.40 ($p < 0.001$ and 95 [0.21-0.55]) for the right eye series and 0.43 ($p < 0.001$ and IC 95 [0.26-0.58]) for the left eye series. Ninety-one percent (91%) of the right eyes, whose visual acuity measured with the Rossano-Weiss test was -0.18 logMAR, achieved the same visual acuity with the eMOVA test (respectively 95% and 0.18 logMAR for left eyes). The average difference between the two tests was -0.06 logMAR (lower bound: -0.48, upper bound 0.36) for the right eye series and -0.01 logMAR (lower bound: -0.40, upper bound: 0.38) for the left eye series.

	Right eye series	Left eye series
Average visual acuity (in logMAR)		
- Rossano-Weiss test	-0.22	-0.24
- eMOVA test	-0.28	-0.24
Average difference between the two tests	-0.06 [-0.48 - 0.36]	-0.01 [-0.40 - 0.38]
p	0.006 [-0.10 - 0.02]	0.006 [-0.10 - 0.02]
Correlation coefficient	0.40	0.43

Table 2. Main results in logMAR

On the Bland and Altman analysis (Figure 1), the concordance is very good for the highest visual acuities. From visual acuity lower than -0.6 logMAR, the concordance becomes less good. The eMOVA test showed better visual acuity measurements compared to the Rossano-Weiss in low visual acuity patients. The eMOVA test overestimated the visual acuity of 0.06 logMAR compared to the Rossano-Weiss for the right eye series and 0.01 logMAR for the left eye series. Using the lower and upper limits, we find that at most the difference in values obtained between the two tests was -0.48 logMAR for the right eye series (Figure 2) and -0.40 logMAR for the left eye series (Figure 3).

The average difference between the two measurements was -0.06 logMAR in favor of the eMOVA test using the Wilcoxon test. This difference was statistically significant ($p = 0.006$). The 95% confidence interval of this difference was $[-0.10 - 0.02]$. These results were the same for both series. This means that at most, the difference in visual acuity measured between the two tests would be 0.10 logMAR. The results of the two concordance and superiority tests show the same trend: the eMOVA test statistically significantly overestimates visual acuity. This difference, however, is not clinically relevant as it would be at most 0.06 logMAR. Analysis of the Bland and Altman graphs shows that measurement concordance decreases for low visual acuity. The concordance is good for the visual acuities between 0 and -0.6 logMAR and becomes lower for the visual acuities lower than -0.6 logMAR (Figure 2). This trend is also found for the second series (Figure 3).

- Secondary judgment criteria

The results are shown in Table 3. Eighty-four percent (84%) of all children had an understanding score of 5. Eighty-one percent (81%) of all children had an attention score of 5. Eighty-four percent (84%) of all children had a distance score greater than or equal to 4. There was no statistically significant difference between the two tests. The average difference in duration of assessment of visual acuity in both eyes between the two tests is 21 seconds. The minimum duration is 11 seconds for the Rossano-Weiss test and 23 seconds for the eMOVA test. The maximum duration is 340 seconds for the Rossano-Weiss test and 174 seconds for the eMOVA test. These differences are statistically significant ($p < 0.001$). Overall, for both tests, we notice that the child's discomfort increases during the

test. The average FLACC scores obtained before / during / after the test were all three lower with the eMOVA test. The eMOVA test is less stressful for the child than the Rossano-Weiss test and this difference is statistically significant ($p = 0.01$).

	Rossano-Weiss	eMOVA	p
Understanding	4.8	4.8	0.11
Attention	4.7	4.8	0.26
Respect of distance	4.4	4.3	0.72
Duration	43	64	<0.001
Total FLACC	0.3	0.1	0.01

Table 3. Comparison of secondary judgment criteria.

- Test parameters

The reproducibility of the eMOVA test was calculated on a sample of 30 eyes (both eyes of 15 children) that performed the eMOVA test twice in a row under identical conditions. The reproducibility of the eMOVA test was very good with an intra class correlation coefficient of 0.93 (95% CI [0.87-0.97]). Considering the Rossano-Weiss as the gold standard, we have defined as amblyopic any child with a monocular acuity less than or equal to 6/10 or with a difference in visual acuity greater than or equal to 2/10 between the two eyes. The sensitivity of the eMOVA test was 56% and its specificity 88%. The negative predictive value of the test was 90% and its positive predictive value 53%. The accuracy of the eMOVA test was 82%.

eMOVA	Rossano-Weiss	M+	M-	Total
M+		10	8	18
M-		9	69	78
Total		19	77	96

Table 4. Distribution of true positives, true negatives, false positives and false negatives (M+ corresponds to the presence of amblyopia and M- to its absence).

- Choice of preferred test

The eMOVA test was mostly chosen by parents and children when we asked them which of the two tests they would prefer to use in a future consultation. Eighty-seven percent (87% or 84/96) of the children and 80% (or 77/96) of the parents chose the eMOVA test.

- Sequence effect

No sequence effect was highlighted. There was no statistically significant difference depending on the order of completion of the two tests which limits the bias of our study ($p=0.61$).

Discussion

Our study showed the interest of the eMOVA test as a screening test for amblyopia in children from 3 to 8 years old. It showed its reliability with a correct agreement with the Rossano-Weiss test (ICC 0.43), 95% correspondence for the best visual acuity and a mean difference in visual acuity of 0.06 logMAR between the two tests. These results are good compared to those of studies that have developed similar tests (21,22). The eMOVA test is reproducible (ICC 0.93) and simple. Indeed the understanding of the test was high (score of 4.8/5) and the testability of 97% in our sample which is very good in comparison with the main tests having shown their good performance (23,24). However, this comparison should be made with caution in view of the variability of the ages present in the samples presented by this studies. Studies of only children under 10 are not the most common (25–32). Their comparison made it possible to highlight the speed of realization of the eMOVA test (21,22). The test was chosen as preferred by 87% of children and 80% of parents. The difficulty was less, as shown by the FLACC scale. The eMOVA test is fast, with an average duration of one minute, thus it avoids any risk related to LEDs exposure(33) . The eMOVA test

is inexpensive compared to the price of test projectors and Retinomax. EMOVA strengths are the measurement of angular visual acuity via Raskin's E, its accessibility and the automation of the test. The mobility of the test could allow its use by non-medical health professionals and this is a major step forward. The possibility of being self-directed at home by the child or his parents had to be explored and could increase screening capacity and at-home monitoring progress in the rehabilitation of amblyopia (25,31). The computerization of the data may also have an epidemiological interest (34). The eMOVA test, however, showed some limitations with a lower concordance for the lowest visual acuity, but these data are consistent with those in the literature for similar studies (26,35,36). In our sample, only 16% of children using eMOVA had their first visit. There was 34% strabismus and the prevalence of amblyopia was 19% considering the Rossano-Weiss test as gold standard. These incidence of amblyopia and strabismus are much higher than those found in the literature (25,37–55). This is explained because these children were visiting a specialized ophthalmic-pediatric center. This bias may limit the extrapolation of our results to screening conditions. In addition, most of the children included had already benefited from previous consultations. Only 16% of the children in our sample came for the first time. The remaining 84% were therefore trained in the Rossano-Weiss test, which can create a bias related to a learning effect. However our study has the merit of being a study of real life contrary to what one could find in the literature (21). The isolated optotype presentation decreases the contour interaction effect and may overestimate visual acuity compared to scales including a linear presentation of the optotypes. The eMOVA test presents the possible choices for pairing in groups of four, but the optotype to be recognized is presented in isolation. This phenomenon could help to explain the overestimation of visual acuity with the eMOVA test. Several studies have sought to determine the optimal technical characteristics of tablets for the evaluation of visual acuity and to show the interest of these media (56–58). Further studies are needed to verify whether the visual acuity measurements obtained with the eMOVA test can be comparable on tablets of different models and brands and how it could be used at home. The choice of gold standard can also be discussed. The correct level of concordance found in our study shows the lack of accuracy between the two tests but does not tell us about the test whose measurements are closest to reality. No visual acuity test is perfect and the Rossano-Weiss test has its own flaws. The eMOVA test should be compared to other scales of visual acuity and especially to the ETDRS scale to better define its limits. Our study led to the development of a simple method for assessing visual acuity of children on tablets. It revealed a correct match of the eMova test with the reference method we use in common practice, the Rossano-Weiss test. This new test has been successfully submitted to children with a high rate of acceptability from both children and their parents. Further studies are needed to evaluate the value of this test on a larger scale.

Conclusions

The eMOVA test appears as a reliable method of assessing visual acuity that could be used both in consultation and in the future on a larger scale in the context of screening as well as for the care of the most difficult children.

Declarations

- Ethics approval and consent to participate

The study and data collection conformed to all local laws and were compliant with the principles of the Declaration of Helsinki. Local institutional ethical comity approved the study. Parents' or legal guardian' and child's consent have been obtained.

- Consent to publish

All the authors approved the submitted version and consent for publication. No details, images or videos relating to an individual person can be found in this article.

- Availability of data and materials

The data directly supporting the publication can be accessed on request to the first author.

- Competing interests

The Authors declare that there is no conflict of interest.

- Funding

The Authors declare that they received no specific funding for this work.

- Author's Contributions

EDF contributed to the main idea of the study. NS and AS participated in the design and implementation of the study. NS collected, analyzed and interpreted all of the data. CSS authorized the study and made its patients available for pediatric ophthalmology consultations.· AcknowledgementsThe authors thank the team of orthoptists 'team who helped carry out the tests and collect the data.

Abbreviations

eMOVA = electronic Measurement Of Visual Acuity
PDA= palmtop computer
AMD = age macular degeneration
FLACC scale = Face Legs Activity Cry Consolability scale
ICC = intra-class correlation coefficient
ETDRS scale = Early Treatment Diabetic Retinopathy Study scale

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Figures



Figure 1

eMOVA test screen

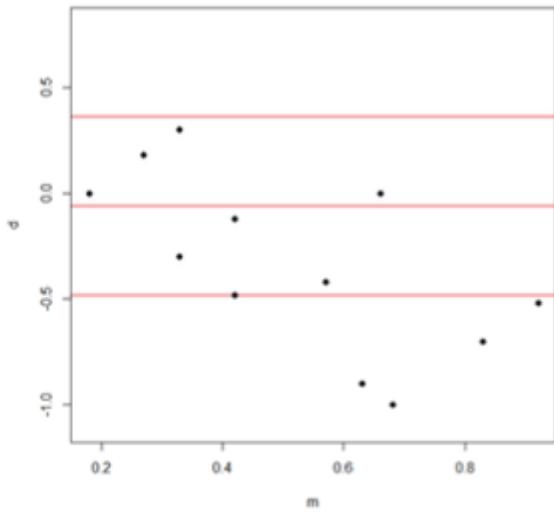


Figure 2

Bland and Altman analysis: quantitative concordance analysis for the visual acuity of the right eye (in logMAR).

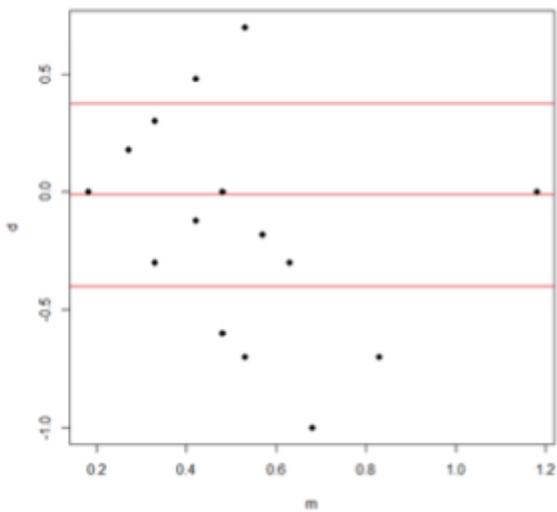


Figure 3

Bland and Altman analysis : quantitative concordance analysis for the visual acuity of the left eye (in logMAR).