• Clinical Research •

A new visual acuity test on touchpad for vision screening in children

Elsa Di Foggia[1], Noémie Stoll[2], Hélène Meunier[3], Adam Rimelé[4], Pascal Ance[4], Pierre−Henri Moreau[4], Claude Speeg−Schatz[1], Arnaud Sauer[1]

[1]Ophthalmology Department, CHU Strasbourg, Strasbourg, Alsace 67091, France

[2]Ophthalmology Department, CH Colmar, Colmar, Alsace 68024, France

[3]Cognitive and Adaptative Neuroscience Laboratory, Strasbourg, Alsace 67000, France

[4]Plateforme SILABE, Strasbourg University, Alsace 67207, France

Correspondence to: Elsa Di Foggia. Ophthalmology Department, NHC Strasbourg, 1 Quai Louis Pasteur, Strasbourg 67000, France. elsadifoggia@gmail.com

Abstract

● **AIM:** To validate a visual acuity (VA) test application on touchpad in the screening of pediatric population by comparing VA results obtained with conventional tests.

● **METHODS:** A cohort of 101 patients, 44 girls and 57 boys with a median of 6.5 years old (3-10 years of age), presenting for eye examinations in Ophthalmology Department (Strasbourg, France) between November 1st, 2018, and February 1st, 2019 were enrolled. Monocular and binocular VA testing was performed on the subject using both a standard test and the touchpad application (Monoyer, "E" or, Pigassou depending of children's capacities). Patients were excluded if they were physically or mentally unable to use the touchpad. The duration of each tests, the painfulness, the comprehension, the attention of children during the test and test's preferences were also evaluated.

● **RESULTS:** There was a good linear correlation and intra-class correlation coefficient [ICC=0.50 (0.34, 0.64) for binocular acuity, 0.74 (0.64, 0.82) for right eyes and 0.525 (0.37, 0.66) for left eye]. The standard errors of measurement were very low (0.08, 0.05, 0.08 for binocular VA, right eyes VA and left eyes VA, respectively). There was no difference between two tests for right eye (P=0.126), left eye (P=0.098) and binocular acuity (P=0.085). Non inferiority was proved for all binocular [-0.06 (-0.09, -0.03)], right eye [-0.04 (-0.07, -0.01)] and left eye [-0.06 (-0.09, -0.02)] VA. The sensitivity and specificity, which correspond to the ability for our app to detect amblyopia, were 92% and 80% respectively.

● **CONCLUSION:** Our touchpad application represents an efficient and valid test of VA in children with a high specificity to detect visual impairment.

● **KEYWORDS:** visual acuity; application; screening; children

INTRODUCTION

Amblyopia, defined as a difference in best-corrected visual acuity (BCVA) between the two eyes of 0.20 logMAR (2 lines on an acuity chart), occurs during the critical period of brain development[1]. Its prevention and treatment are only effective during childhood. Depending on its definition, prevalence varies between 0.4% and 5.6% in developed countries[1-5]. It may be due to either organic pathology of the visual pathways, visual deprivation or, functional abnormalities (mainly anisometropia or strabismus)[1].

Ametropia represent the most important risk factor of amblyopia with a prevalence of 23% in a large American study in 2013[3], and 19 million children are affected by visual impairments worldwide[6]. As a matter of fact, uncorrected refractive errors are a real public health issue with an estimated cost of US$ 202 000 million annually according to the World Health Organization in 2012[6]. Poor vision has also negative social, health, educational and economic consequences. Early identification and treatment of eye conditions reduces the prevalence of visual impairment hence the importance of effective screening during childhood[7]. Nevertheless, depending on the country, the ease of access to visual specialists (ophthalmologists and orthoptists) varies.

The French program for visual impairment screening is not systematic. Only two ophthalmologic exams are mandatory, the first one during the first week after birth, the second one at the age of 6. However, in some regions, a program including

a visual acuity (VA) test does exist in nursery and elementary schools and is carried out by nurses, orthoptists or doctors.

Actually, several screening initiatives are offered throughout the world to enable a large number of children to benefit from a simple and rapid test for early diagnosis of amblyopia[8-9]. Increased access and use of smartphones and tablets has recently led to the development of many screening or VA tests applications in several countries[10-12]. Further development and expansion of such application would enable a larger number of people to gain access to screening of visual disorders. The perspective is all the more interesting as adherence to such screening method is high among children.

With the aim of improving screening among the pediatric population, a VA test application available on Android tablets has been developed through the corporation grouping the Ophthalmology Department of Strasbourg University Hospital and the University of Strasbourg in France. At first, the study focused on the VA test from near with a first application created, called the E-Mova test. The results of this study demonstrated a great reliability of the test which permitted us to create a brand new application targeting distance vision[13].

In order to validate this new test as a screening method, a comparative study with the standards VA tests used in current clinical practice with children from 3 to 10 years old was carried out in Strasbourg University Hospital.

SUBJECTS AND METHODS

Ethical Approval The study adhered to the tenets of the Declaration of Helsinki and was approved by Strasbourg University and Strasbourg's University Hospital Center Ethics Committees. Inform consent was obtained from all participants and their parents. The risks and benefits for participation in the study were explained in French.

Design Study, Participants This prospective monocentric study was realized at the Ophthalmology Pediatric Department of the Strasbourg's University Hospital in France. Children were recruited prospectively from November 1st, 2018 to February 1st, 2019 during pediatrics consultations. All patients between 3 and 10 years old, with sufficient cognitive and physical abilities to understand the test, were included consecutively, regardless of their pathologies. Exclusion criteria included handicap such as incapacity to press on the tablet, mental retardation, the refusal of parents or children to participate and a previous participation to the test.

Procedure Each participant has been tested first, with a standard acuity test at 5 meters' distance, then, with Snellen E application with touchpad 3 meters away. Test administrator was not masked to the results of the first test during the administration of the second test.

Standard acuity test was subjectively determined by the examiner depending of the age, maturity and capacities of the children. Also, Monoyer scale, Raskin's E or Pigassou test were carried out in this order, according to the cooperation of the child. Decimals values were converted in logMAR. VA was measured with glasses if worn, or with total optic correction if children were dilated by cycloplegia. A skin patch was used to hide the eye during measurement of monocular VA. Binocular VA was tested first, followed by right eye and left eye, always in the same order.

Additional data notes were collected such as the ages, reason for consultation, pathology (strabismus, amblyopia, ametropia *etc*.), the presence of an optic correction, the presence of a cycloplegia, the access of a smartphone or touchpad at home. Binocular VA, monocular VA, tests duration with each test, were consigned on a specific data chart. Tablets results data was saved directly in the patient record in the touchpad. Results with conventional test were noted in the clinical chart. Comprehension, attention, test's painfulness with FLACC Scale were also subjectively evaluated by the examiner for both tests. It consisted in giving a score from 0 to 5 for each characteristic, 0/5 corresponding to the worst score and 5/5 to the best score. Once the test was completed, the participants and their parents were asked for which VA test they would prefer to be tested with the next time and the reasons why.

Touchpad Characteristics The application was created by engineers and researchers of Strasbourg University and developed to be used on Android operating system. According to this specificity, we have chosen a Samsung Galaxy Tab A device equipped with a 7 inches' touchscreen which features sufficient quality of contrast and resolution for VA assessment. The app was built in order to permit testing VA with two tablets connected. Both touchpads were paired *via* Bluetooth, one was considered as a display touchpad projecting the items whereas the other one was used to provide the answer. Two testing distance options were available in the app which permitted to displace the tablets at either 3 or 5 meters away depending of the size of the room. The intensity of the screen was maintained at 100% during the test.

As a VA test displayed by the app, we have chosen Raskin's E isolated optotypes surrounded by 4 bars in order to decrease the crowding effect and to minimize the overestimation of VA as recommended in the study of Holmes *et al*[14]. The application allows a random presentation of the optotypes. The child has to chose the optotype out of three different optotypes presented on the tablet in order to response.

We have voluntarily chosen to remove one of the 2 lateral presentations of the optotypes considering the results obtained on our previous study concerning the measurement of near visual acuity. We had noticed a certain number of errors due to a problem of laterality and not to a problem of vision, some children having difficulties in differentiating between the right

and the left whereas on the contrary no similar error had been detected with the vertical presentation of the optotypes.

Sizes of optotypes were correlated to the distance. The smaller optotype corresponding to VA of 0 logMAR (1.0) was presented at first. 1) If the response was correct, two confirmations were necessary to validate the VA, therefore, two extras optotypes with different orientations were presented. 2) If there was a failure corresponding to 0 logMAR (1.0) acuity line, an optotype corresponding to 0.3 logMAR (0.5) was presented, followed by 0.2 logMAR (0.63) 0.16 logMAR (0.7) and so on to 0 logMAR (1.0). The line of VA was valid after 2 confirmations. A failure at one level would automatically induce the presentation of a higher level size optotype for double confirmation. 3) If there was a failure corresponding to 0.3 logMAR (0.5) acuity line, an optotype corresponding to 1 logMAR (0.1) was presented, followed by 0.7 logMAR (0.2), 0.5 logMAR (0.3) and so on until new failure occurred, as previously described. To make the test more fun, smileys and sound animations accompany the good or bad answers. Interface of the application is presented in Figure 1.

Outcomes The primary outcome was the correlation of VA noted in decimal and logarithmic scale between the two tests. The main secondary outcome was the time taken by children to make the tests. We also compared painfulness, understanding, attention and behavior of the children during testing and finally preferences between the application and standard tests.

Statistical Analysis We calculated the sample size for primary outcome assuming a power of 90% with 105 children required. All analyses were performed with Bayesian method. For the initial evaluation, we realized a concordance study to primary outcome analysis to test equivalence of both VA tests (standards *vs* app). We used Bland-Altman method and we calculated intraclass correlation coefficient for continue quantitative variables with their 95% credible intervals. VA, painfulness, attention and comprehension between both VA tests were compared with mixed beta regression model. Duration between two tests was compared with mixed gamma regression model. The probability that the coefficient associated with the tests was greater than 0 was calculated. It was considered as no difference a probability comprised between 0.025 and 0.975. Finally, a non-inferiority study was realized by calculating the mean and its credible interval regarding the posterior distribution of the difference between both tests. The non-inferiority margin was fixed at 1 for decimal scale and 0.10 for logarithmic scale. Statistical analyses were performed using the R software 2018 version 3.5.0.

RESULTS

Study Population Description A total of 106 children were recruited between November 1st, 2018, and February 1st, 2019.
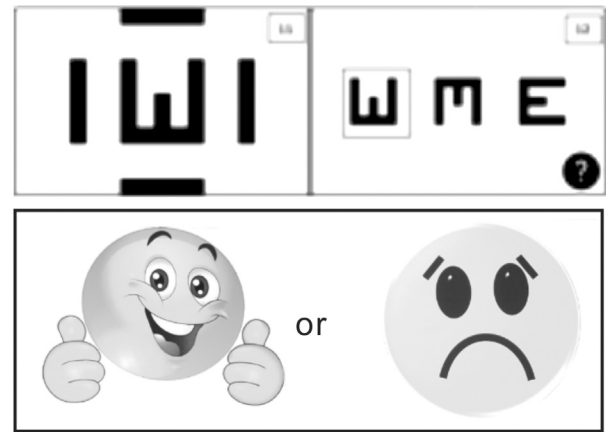

Figure 1 Interface of the application on touchpad Optotypes surrounded by bars on projection tablet and optotypes choices on answer tablet, and smileys accompanying good or bad answers.

Table 1 Population characteristics

Reasons for consultations	n (%)
Screening	66 (65)
Strabismus	21 (21)
Cataract	4 (4)
Amblyopia	4 (4)
Hight myopia	1 (1)
Prematurity	1 (1)
Sturge-Weber	1 (1)
Uveitis	1 (1)
Retinoblastoma	1 (1)
Ptosis	1 (1)
Total	101 (100)

Cohort was composed of 44 (41%) of girls and 57 (59%) of boys. The median of age was 6.5 years old [59 (58%) >6y]. Five children were excluded of the analysis because of an incapacity to finish one of the tests. All patients had access to a tablet at home or at school.

Prevalence of visual impairment, as measured by standard acuity test (defined by at least one eyes <6/10 or difference between the two eyes >2 lines) was 22% (*n*=22). The main characteristics of population and parameters are described in Table 1.

Primary Outcome Measure The average of VA in conventional test was 0.13 logMAR (0.81 in Monoyer Scale) for right eyes, 0.11 (0.84) for left eyes and 0.07 (0.89) for binocular acuity compared to respectively 0.16 (0.76 Monoyer), 0.16 (0.76) and 0.12 (0.8) with tablets. The results between both tests were comparable for monocular left, right and binocular VA. Standard errors were very low for all visual acuities; 0.081, 0.052, 0.083 for binocular VA, right eyes VA and left eyes VA respectively, which confirm the precision of our measures.

To detect a unilateral amblyopia, defined as a VA inferior to 0.2 logMAR or a difference superior to 2 lines between
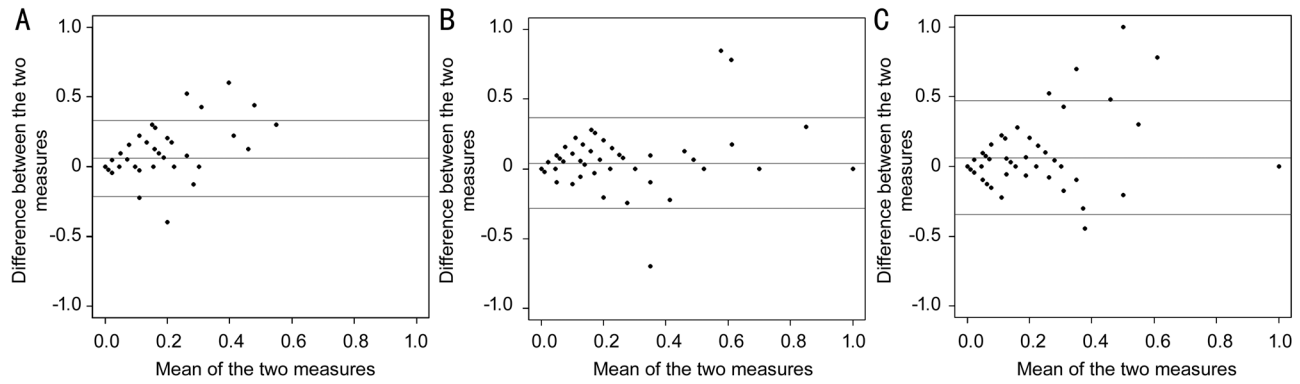
Figure 2 Bland-Altman analysis A: Binocular VA (-logMAR); B: VA of right eyes; C: VA of left eyes (-logMAR).

both eyes, our application shown a good accuracy with a high sensitivity (92%) and a good specificity (80%). Both predictive positive and negative values were respectively 52% and 99%. The positive likelihood ratio was 4.5 and the negative likelihood ratio was 0.1. In summary, the tablet-based VA test correctly identified 92% of visual impairment on the children assessed.

To test the equivalence between both VA tests, a concordance analysis was performed first. Intraclass correlation coefficients (ICC) with 95% credible intervals were 0.50 (0.34, 0.64) for binocular acuity, 0.74 (0.64, 0.82) for VA of right eye and 0.53 (0.37, 0.66) for VA of left eye. Interestingly, the lower the intra-subject variability was when compared to the variability between subjects, the higher was the intra-class correlation meaning that both present a good correlation in terms of variability. Bland-Altman analysis shown a very good concordance for high values of VA for all series. Although still correct, concordance was worse for low VA (0.4 logMAR or less), particularly for the left eye (Figure 2). This result can be explained by the fact that the left eye was always tested last.

In a second time, VA values measured with tablet and standard tests were compared with mixed beta regression model. For each variable, the probability that one variable is greater than 0 was calculated. The results shown no difference between both tests for right eye (P=0.126), left eye (P=0.098) and binocular acuity (P=0.085).

Non inferiority was proved for all binocular [-0.06 (-0.09, -0.03)], right eye [-0.04 (-0.07, -0.01)] and left eye [-0.06 (-0.09, -0.02)] VA logMAR values with a threshold of 0.1 logMAR (Figure 3).

Secondary Outcome The results of secondary outcome are described in Table 2. The total test duration for both standard and tablet test was not statistically different (P=0.969). Values of comprehension and attention were not statistically different and there was no painfulness for both tests.

Another interesting result was the preference rate for the VA test on tablets. Ninety-five percent of children and 81% of parents had preferred to be assessed with the application.
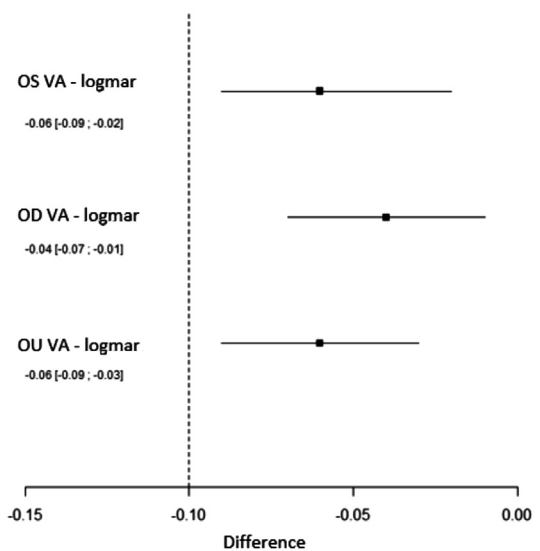

Figure 3 Non inferiority study with a threshold of 0.1 logMAR.

Table 2 Secondary outcomes

Secondary outcomes	n	Average (min-max)	Median	P
Duration S (s)	101	159 (10-686)	132	0.969[a]
Duration T (s)		138 (22-353)	134	
Comprehension S (/5)	101	4.68		0.088[a]
Comprehension T (/5)		4.60		
Attention S	101	4.47		0.042[a]
Attention T		4.61		
FLACC S (/10)	101	0.1		0.576[a]
FLACC T (/10)		0.1		

S: Standard test; T: Tablet application; FLACC: Test's painfulness with FLACC Scale. P: Probability that the variable is greater than 0.
[a]Non significant (between 0.025 and 0.975).

Principally, they found the test playful, fun, and more in line with our current modern society. However, when the standard VA tests were preferred, the main reason was that tablets might present a "risk" regarding the eyes of their children. A part of parents (10%) did not have any preferences.

DISCUSSION
The objective of our study was to test our application during pediatric ophthalmic consultations and to compare it with the

standard methods used for acuity testing in our department in order to be in a position to validate it in real screening situation.

The results obtained demonstrate a good correlation in terms of VA between the conventional tests (Monoyer, the Snellen-E, Pigassou) and the one carried out on a tablet. Such results are all the more encouraging as very few existing applications have indeed been tested on pediatric cohort and validated, while several studies on adult population exist[12,15-18]. A 2012 study called The Eye Phone Study assessed the reliability of 11 applications using the Snellen Scale. None of the applications were identified as being capable of measuring VA effectively[11]. The Handy Eye Check using the Handy Eye Chart according to the Amblyopia Treatment Study recommendations was the application featuring the highest correlation rate (r=0.92)[14,19]. This correlation, higher than the one featured in our own test, needs to be put in perspective considering the smaller number of children tested and the wider age scale of those tested (60 children included from 6 to 18 years of age), including children as old as 18[19]. Furthermore, a single eye was only tested in the Handy Eye Check study whereas each eye and binocular VA were registered in our study.

The gold standard selected for our study, *i.e.* the Monoyer Scale, the Snellen-E, the Pigassou, also need to be taken into account as all of the above-mentioned have their own limitations and lack precision in VA measurement[20]. These tests were chosen because they correspond to those used routinely during our consultations. As a matter of fact, decimal scales together with their logMAR conversions have exclusively been used in our study when, ideally, logarithmic scales like the ETDRS should have been used for more precision[20].

This study showed the non-inferiority of the test of VA from a distance on a tablet compared to the tests used in routine. The originality of this study is the use of a distance vision test. Most of the studies carried out with children assess their near VA, which can be useful as part of the follow-up of an amblyopia management but less interesting as part of a screening process[21]. The results obtained cannot easily be compared with those obtained in our distance vision test.

Studies carried out with large groups of children have evaluated the idea of implementing a screening program at school, the PEEK School Eye Health System, initially validated on a group of adults in Kenya. This program included a VA assessment through a mobile application together with an automatic communication system alerting parents in case of their children's VA being less than 6/10. The program was evaluated in Kenya and in Paraguay in 2018 with varied results[8-9,22]. On the one hand, evaluation in Kenya highlighted a strong adherence to the Peek School Eye Health System with more parents accepting to accompany their children to undergo the assessment in hospital. On the other hand, the evaluation in Paraguay demonstrated an insufficient sensitivity of the test, considering the large number of children with unidentified refractive errors[8-9]. In our study, the high percentage accounting for the children expressing a preference for the use of touchpads (95%) confirms easy adherence of children to this type of test. This could facilitate screening at school. Likewise, understanding and attention rates with children were excellent (with average scores respectively 4.60 and 4.61 out of 5 and no difference with the standard test). The test is relatively fast, particularly for high VA, with no extra painfulness involved (very low FLACC score), which provides the test with a definite advantage. We could therefore in the future imagine a similar system to the Peek acuity program to improve the usefulness of our application with automatic messaging displayed in case of ophthalmologic consultation needed.

Finally, the sensitivity rate of our test was high (92%) with a good specificity, which is ideal to ensure the effectiveness of our app to detect amblyopia. As a matter of fact, the objective of such test is to detect the maximum number of people visually impaired and only two children with proven amblyopia had not been detected by our own test. However, as previously pointed out, conventional tests with an arrhythmic scale are not perfect. There are no precise data in the literature for their sensitivities for the detection of amblyopia. In our study, it was close to 98% which is comparable to our application. This results were similar to those found in the large study of Rono *et al*[9] with the Peek Acuity test. Moreover, crowding bars are included around each optotypes to improve the detection of amblyopia, in comparison to testing with single letters alone, although differences of opinion exist[23].

The absence of double-blind process reduces the impact of our study. To overcome this, we started with the conventional VA test because the final VA on the touchpads cannot be influenced by the examiners, the child pressing the optotypes himself. To our knowledge regarding the literature, our test is the only distance VA test that allows the child to type the answer himself without being influenced[8-9,24]. Having said that, we did notice that the child's motivation and understanding levels could be increased with the operator's encouragements. Likewise, previous training did generally facilitate the conditions under which the test was carried out. This was done with children under the age of 6 only. Such a mock-up training test should maybe be carried out with all children.

Another setback of our application is that it does not enable us to test low VA less than 1/10ᵉ, unlike other studies[22], although such date is not as important when screening.

Our study thus presents some limitations we detailed previously. Having chosen to use a decimal scale as VA index

can increase the risk of committing errors in data processing when values are converted into a logarithmic scale. Also, we wanted our study to be as close as possible to real life testing without double blind conditions, letting the experimenter choosing between standards VA tests in accordance to child capacities. Performing under this condition could potentially bias the data power by not using the same standard VA test for the whole study. In addition, in a perspective of expanding the use of our application in different medical centers, an evaluation of the cost to implement such a device is also missing. Indeed, having the application requesting two connected tablets might potentially limit poorer regions in developing a more modern vision screening method regarding the investment to make.

Another point to highlight is the handling of tablets to gain reliable VA results. According to our study, the most important thing is to respect the distance between the two connected objects in order to be sure not to under diagnose visual disturbances if the two tablets are too close for example. However, we did not find any other usage constraints, in particular for the child's response on the tablet, the handling remains easy.

Finally, we made a point of choosing to highlight the concordance analysis that enables us to thoroughly check if the VA of a child tested with the application is in line with the reference test. Indeed, a non-inferiority trial, as realized in similar studies, could imply the risk of a poor concordance, due to comparing globally the VA averages rather than the average for a particular patient[25-26]. Our results demonstrate that, as far as the VA and the duration of the test are concerned, the touchpad test figures are not inferior to the conventional test. Both the concordance analysis and the non-inferiority study prove the validity of this VA measurement application. In addition, our system allows automation of the testing protocol with an automatic determination of the level of optotypes presentation after children's responses, the ability to randomize letters and an automated scoring of VA.

The advantage is therefore for children to gain access to an easily available and playful screening test that is user-friendly enough to enable the child not to rely on his/her language skills. It is particularly interesting on younger child who can be shy and present some difficulties in participating in the conventional VA tests. Indeed, we noticed that these children answered easier with tablet. So, we consider that our application can be reliably used with children from 4 years old and probably younger in view of our results.

A collaboration has started in 2019 between the Ophthalmology Department of Strasbourg University Hospital, Strasbourg University and Strasbourg Council (Eurometropole) in order to assess ergonomics of modern VA tests in medical practices.

Eye screening sessions will be conducted on a larger cohort in 2020 with a use of the application in Strasbourg pre and primary schools.

Subsequently, the use of the application could be expanded to public and allow families to perform VA tests at home as a pre-diagnosis tool. According to the results of the test, a message could be delivered informing about the need or not to seek for an ophthalmologist.

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