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TITLE: Age norms for grating acuity and contrast sensitivity in children using eye tracking technology.

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KEY MESSAGES:

- Visual acuity is the most used method to assess visual function in children. Contrast sensitivity complements the information provided for visual acuity, but it is not commonly used in clinical practice.
- Digital devices are increasingly used as a method to evaluate visual function, due to multiple advantages. Testing with these devices can improve the evaluation of visual development in children from a few months of age.
- Visual acuity and contrast sensitivity tests, using eye tracking technology, are able to measure visual function in children across a wide range of ages, objectively, quickly and without need of an experienced examiner.

ABSTRACT

Purpose:

To report age-normative values for grating visual acuity and contrast sensitivity in healthy children using a digital device with eye tracking technology and to validate the grating acuity test.

Methods:

In the first project of the study, we examined healthy children aged between 6 months and 7 years with normal ophthalmological assessment. Grating visual acuity (VA) and contrast sensitivity (CS) were assessed using a preferential gaze paradigm with a DIVE (Device for an Integral Visual Examination) assisted with eye tracking technology to provide age norms. For the validation project, we compared LEA grating test (LGT) with DIVE VA in a group of children aged between 6 months and 4 years with normal and abnormal visual development.

Results:

Fifty-seven children (2.86 \pm 1.55 years) were examined with DIVE VA test and 44 successfully completed DIVE CS test (3.06 \pm 1.41 years). Both, VA and CS values increased with age, mainly along the first two years of life. Sixty-nine patients (1.34 \pm 0.61 years) were included in the DIVE VA test validation. The mean difference between LGT and DIVE VA was -1.05 \pm 4.54 cpd with 95% limits of agreement (LoA) of -9.95 – 7.84 cpd. Agreement between the two tests was higher in children younger than 1 year with a mean difference of -0.19 \pm 4.02 cpd.

Conclusions:

DIVE is an automatic, objective and reliable tool to assess several visual function parameters in children and it has good agreement with classical VA tests, especially for the first stage of life.

KEY WORDS: Childhood; Visual Development; Visual Acuity; Contrast Sensitivity; Eye tracking.

INTRODUCTION

The child population affected by visual impairment was approximately 19 million children in 2012 [1]. Identification of any potential cause of visual impairment at early stages is critical for these children to follow a proper visual development [2, 3]. This is, therefore, the basis underlying any vision screening program performed by pediatricians, ophthalmologists and optometrists [4, 5].

The most commonly used method for a first assessment of the visual function is visual acuity (VA), which evaluates the capacity to resolve the smallest stimulus at a maximum contrast level, but it is not fully representative of real settings, because maximum contrast levels are not the rule in daily life [6]. Contrast sensitivity (CS) indicates the minimum luminance differences that a patient is able to detect and offers valuable information about the visual quality with which they perceive their environment. It complements information provided by VA and can help to detect ocular pathologies and cerebral pathways disorders [7–9]. However, contrast sensitivity is rarely assessed in clinical practice, mainly due to lack of adequate tests for certain patients.

This is especially remarkable for children, whose lack of collaboration or understanding make most of diagnostic tools inadequate or inaccurate. Therefore, in order to accurately evaluate their visual function, tests adapted to their age, visual function and cognitive abilities are required.

There are different validated tests used to measure visual function in children under the age of 2 years. VA can be assessed by means of: LEA gratings test (LGT) [10], Teller acuity cards [11] and Keller acuity cards [12]; while Hidden Heidy and Lea Contrast sensitivity tests are used for assessing CS [13, 14]. All of them are based on the forced-choice preferential looking paradigm (FPL) [15–17] which requires the presence of an experience examiner to analyze child's answers.

Nowadays, digital devices are more and more used to examine visual function and their results have been demonstrated to be comparable with traditional methods [18–21]. The main advantages are a greater control over the characteristics of the presented stimuli, higher accuracy, more objective assessment of children responses to the stimuli [18] and the possibility of including different tests in a single device, and thus reducing the exploration time. Furthermore, attention to digital tests seem to be higher than to analogic ones in very young children, improving the reliability of the test.

Eye-tracking technology is currently an emerging tool in vision sciences, and in many other research areas [22–24]. It uses infrared light to record the reflection of different ocular structures (cornea, pupil or both) [25] and thus determine the position of the patient's eyes and measure their movements and fixations on a screen. The eye-tracker (ET) records and saves objective information from the patient's gaze even in non-collaborative patients, and patients with motor and verbal disabilities [26–28].

With the aim of overcoming the barriers of current visual diagnosis in children, we developed DIVE (Device for an Integral Visual Examination, from DIVE Medical Start-up), a digital device capable of performing visual assessment in children, in an accurate and customized way.

The goal of our study was to validate the grating VA test from DIVE and to report normal reference ranges of VA and CS throughout childhood.

METHODS

The present study included two different projects. The first project reports normal values of VA and CS measured with DIVE in a group of children with normal visual development. In the second part of the study, we intended to validate DIVE VA test comparing it with the analogic LGT in a group of children with visual normal and abnormal development.

Participants

All participants of this study were recruited from our Pediatric Ophthalmology Unit (Miguel Servet University Hospital, Zaragoza - Spain). Children with normal visual development were recruited from siblings of children visited in the unit or healthy children referred for a vision screening. The parents of all participants had to sign a written informed consent to be included in the study. All procedures during the study adhered to the tenets of the Declaration of Helsinki and were approved by the local ethics committee: CEICA(PI15/0157).

Project 1: Determination of VA and CS normal reference values.

Children aged between 6 months and 7 years were eligible. None of them presented known ocular pathology (other than minor refractive error considered as spherical equivalent (SE) lower 3 diopters (D) or a cylinder lower than 2 D), had previous ocular or orbital surgery, or were affected by neurological or systemic diseases. The gestational age and birthweight were within normal values: > 37 weeks at birth and birthweight $> 10^{\text{th}}$ centile according to their age and gender. The exclusion criteria were a refractive error higher than 3 D in SE or a cylinder higher than 2 D.

For the evaluation of the VA and CS values, the children were separated into 3 age groups: younger than 2 years, 2-4 years and older than 4 years.

Project 2: Validation of DIVE VA test.

In order to validate the test, we compare the results obtained by DIVE with the outcomes from LGT, which is usually performed in children younger than 3 - 4 years.

In order to validate the test in patients with all conditions and visual function, in addition to healthy patients, children with different ocular pathologies, low birth weight, premature infants and children with medium-high refractive errors were also included.

Examination

Ophthalmological assessment

The ophthalmological assessment included the measurement of VA, fixation, extraocular motility, biomicroscopy, refraction under cycloplegia and fundus examination. The VA (both monocular and binocular, whenever possible) was measured by a pediatric ophthalmologist according to the age of patient or level of cooperation, with the LGT (based on FPL paradigm) at 57 cm, in younger than 24 months (or nonverbal patients), LEA symbols Chart at 3 meters distance for children between 2 and 5 years and letter optotypes (ETDRS Visual Acuity Chart) at 3 meters distance when they were literate.

To perform the LGT, an examiner presented two paddles to the patient, one with a pattern of vertical grids alternating black and white stripes with 100% contrast (e.g., 1.0 cpcm one cycle or pair of black and white lines on one centimeter of the surface) and the other with a uniform grey background. The examiner determined whether the stimulus was seen or not by the child by observing the first gaze direction. The difficulty to see the stimulus progressively increased (higher spatial frequency), until the infant was no longer able to resolve it. The examiner repeated each stimulus presentation until they confirm the assessment. The grating acuity value was noted in cycles per degree of visual angle (cpd).

VA and CS assessments with DIVE

-Equipment:

The digital binocular assessment of VA and CS was performed with DIVE, a digital device that performs an automatic examination of the complete visual function even in non-collaborative patients. It has a 12inch high-resolution touchscreen for visual stimuli display, corresponding to a visual angle of 28.46 degrees horizontally and 19.19 degrees vertically.

The device screen was weekly calibrated at maximum brightness, with the Spider X Pro calibrator. D65 illuminant was selected ensuring that the white point luminance of the screen was set at 120 candles per square meter (cd/m²). Gamma value (luminance intensity versus signal voltage) was controlled and stablished at 2.20, as recommended by Aslam [29].

The eye movements were collected by an ET to capture the patient's response to those stimuli, with a maximum temporal resolution of 60 Hz. Gaze direction is calculated using the vector between the center of the pupil and the corneal reflections created by an infrared light.

-Preparation:

The DIVE assessment was performed without spectacles in a dark room where there was only an indirect light source from the back of the device. The patient was sat in front of the device on a fixed chair, so that their eyes were 50 cm from the screen (distance controlled by the ET) and was asked to fixate the different targets. For children under 2 years of age, their parents held them on their laps, keeping their heads gently straight and steady in a comfortable position. The examiner gave the indications while the patient got used to the light conditions before the starting of the test and does not participate any more until the end of the test.

-Calibration and DIVE test:

Before starting DIVE assessment, it was always necessary to calibrate the ET with every patient. For this purpose, each child was asked to fixate on a cartoon of a frog with associated sound, which appeared at 9 different locations across the screen, one at a time. Afterwards, calibration quality was assessed, and the calibration procedure was repeated until the patient achieved a quality of at least three points out of five. Children unable to achieve an acceptable calibration were excluded from the study.

For the grating VA test (DIVE VA test), four circular stimuli were presented simultaneously on a uniform grey background, Figure 1. Three of them (distractors) had a plain grey color, with different luminance between them, and the fourth stimulus (target) that contained a pattern of vertical black and white stripes with maximum contrast between them. Each plate remained on the screen for a maximum of 3 seconds. Based on the duration and characteristics of child's fixation on the screen, the software considered every stimulus as detected or not detected. When a stimulus was properly detected, a positive feedback (consisting of a rotating sounded star) appeared at the center of the correct target to avoid fatigue and increase motivation. Subsequently, the 4 stimuli were replaced by a plain grey screen, with central attention getter to keep the gaze on the screen.

DIVE used a psychophysical method that adapted the plates presented automatically according to the responses of each patient to maximize the precision of the test while reducing its duration.

For the grating CS test (DIVE CS test), shown in Figure 2, the stimuli were generated with vertical bands of a spatial frequency of 0.5 cpd but with different contrast levels. The contrast of each stimulus generated was calculated using Michelson's formula and modified according to the patient's answer using the psychophysical method, in the same way as previously described, until obtaining patient's the contrast threshold. The duration and positive feedback of the stimuli were the same as those reported for DIVE VA test.

To solve lack of attention, when the ET detected data loss, there were a sounded video to recover gaze on the screen. This stimulus disappeared when the ET detected the eyes again.

Statistical analysis

All data were analyzed using SPSS v.25 statistical software (SPSS Inc. Chicago, IL, USA). Descriptive characteristics of VA and CS were reported, for all and each age group, by the mean, standard deviation, confidence interval (95%) and ranges. For the project 1, scatter plots were represented with VA and CS as dependent variables and age as an independent variable, with their corresponding Pearson's correlation coefficient values (ρ). While for project 2, the Bland Altman plot was used to compare the two methods for measuring VA (LGT and DIVE VA test). A p-value <0.05 was considered statistically significant.

RESULTS

Project 1: Determination of VA and CS normal reference values

Sixty patients participated in project 1. Fifty-seven successfully completed the DIVE VA test and 44 the DIVE CS test. Three children did not complete the DIVE VA test due to lack of attention, while CS data could not be measured in 6 children due to lack of collaboration or poor calibration quality. Since this test was implemented later than DIVE VA test, 10 children had no CS assessment.

There were 29 females and 28 males who completed DIVE VA test, with an average age of 2.86 ± 1.55 years and an age range between 0.66 and 6.41 years. The DIVE VA test values for each age groups can be found in Table 1. There was a moderate direct correlation between age and VA, (Pearson's correlation coefficient (ρ) $\rho = 0.56$ (p<0.01)), as shown in Figure 3.

Twenty-one females and 23 males completed the DIVE CS test. Average age was 3.06 ± 1.41 years and the age range was 0.74 to 6.46 years. The DIVE CS test values are shown in Table 2 for each age group. In this case, a strong direct correlation was found between age and CS values (Pearson's correlation coefficient (ρ) $\rho = 0.71$ (p<0.01)), Figure 4.

The average DIVE tests exploration time was 1.83 ± 0.96 min.

Project 2: Validation of DIVE VA test

A total of 74 patients were included in the validation project, with 5 of them excluded because of lack of attention (32 females and 37 males). The mean age in this group was 1.34 ± 0.61 years with an age range between 0.43 and 3.18 years. This sample group was composed by 28 children with normal visual development and 41 with abnormal visual development. Within the group with abnormal visual development, 31 were preterm infants, 5 born with low gestational weight, 3 with congenital cataract and 2 with congenital nystagmus.

The LGT and DIVE VA test outcomes are collected in Table 3. Also, the Bland-Altman values average between two tests: 6.56 ± 2.95 cpd and mean difference between them: -1.05 ± 4.54 cpd (LGT- DIVE VA) were shown in the Table 3 and Figure 5. The 95% limits of agreement (LoA: mean difference ± 1.96 SD) were -9.95 - 7.84 cpd. The mean difference values between two tests (LGT-DIVE VA) for different age groups showed similar behavior between test for the <1-year group (n=25): -0.19 ± 4.02 cpd, while for the 1-2 years (n = 35) and >2 years (n = 9) group there was a greater difference between tests: -1.65 ± 4.37 cpd and -1.12 ± 6.46 cpd respectively, being higher in the 1-2 years group. The mean VA values were higher using the DIVE VA test for all age groups.

Finally, the average duration of the DIVE VA test in this project was 0.86 ± 0.31 min, while the duration of the LGT was estimated to be approximately 3 minutes.

DISCUSSION

Electronic devices and screen-based tests, as the one we used in this study, may enhance visual assessments in children. We report normal reference outcomes for grating VA and CS throughout childhood, using a FPL paradigm and eye-tracking technology to assess children's responses.

Three main methods have been described to assess visual acuity in non-collaborative infants: visually evoked potentials (VEP), optokinetic nystagmus (OKN) and tests based on FPL paradigm [30]. The most popular method in clinical practice is FPL in the different test versions [31]. This psychophysical technique is based on the one described by Fantz [32, 33] and upgraded by Teller et al, who added the concept of forced-choice. This paradigm determines that children prefer to look at a grating pattern stimulus versus a uniform stimulus when both are presented at the same time [16].

Unlike for VA, there is not as much variety in tests commercially available to measure CS, or they are not used on a daily routine in clinical practice. The few CS analogic tests dedicated to children such as Lea low-contrast Symbols and Hiding Heidi low-contrast face test (HHT) require a minimum degree of collaboration, so they are not suitable for children under one year of age [34, 35]. Lea low-contrast Symbols and HHT were developed by Dr. Lea Hyvärinen, being the first CS test specifically adapted for children. These tests determine the threshold of CS showing a series of drawings: house, apple, square, circle (in Lea low-contrast Symbols) and a smiling face (in HHT) that decrease their contrast until the child stops seeing them. The main disadvantage of this type of tests is that the exploration must be done by an examiner with experience in order to be reliable. Other disadvantages are the need for collaboration and not having full control of the spatial frequency of the stimulus being tested for contrast sensitivity (because it is a drawing and not a striped pattern), which can interfere with the results [36].

DIVE is a digital device designed to evaluate both VA and CS through the FPL paradigm, among other visual function tests. Digital devices, such as DIVE, present several advantages over analogic tests. First, the assessment of visual behavior is performed by a standard and objective method, avoiding the influence of the examiner. Secondly, screen-based tests ensure homogeneity of the stimuli and their presentation to the child, and they also enable the use of methods that automatically adapt to the response of the patients. It allows for more accurate and repeatable tests to run in shorter periods of time.

In the first project, VA and CS of children with normal visual development were measured. The first goal was to evaluate the effect of age on visual development. Grating VA improved with age, mainly during the first 2 years of life, when the visual system suffers from more abrupt changes, reaching almost the maturity of the visual system in terms of optical pathway [37]. The mean VA in children aged 2-4 years was twice as high as the mean obtained for children younger than 2. The increment that occurred between the group of 2-4 years and > 4 years was much smaller, it could be due to an increase of the capacity of concentration and attention of the group > 4 years.

Our grating VA results correlated well with those obtained in the study of Leone et al. [38] using Teller acuity cards II. They described a fast increase during the first 24 months of life in children with normal

visual development. This finding is also observed in their sample, where the group aged 27 to 30 months reached 12.08 cpd versus 6.74 cpd from the 12 to 15 months' group. The oldest age group evaluated by Leone was 33 to 36 months and demonstrated lower improvement than in younger ages. On the other hand, the study of Elgohary et al [39], who used LGT for VA, despite presenting the same tendency to increase faster at younger ages (up to 18 months), reported higher VA outcomes than those obtained by Leone and by ourselves. Global differences among them may be due to a higher accuracy of our test, which presented 3 distractors and one target versus one distractor and one target from Elgohary, and a more objective assessment thanks to the removal of the source of bias of human examiners.

The behavior of CS measured with DIVE for a low spatial frequency (0.5 cpd) followed a similar pattern than VA, but with a much more pronounced increase during the first two years of life. Using a logarithmic scale, mean values were 0.89 for children younger than 2 years, 1.62 for 2 to 4 years and 2.17 for children older than 4 years. Since we are using a logarithmic scale to report the contrast sensitivity data, large differences between the first two groups mean a much larger difference in the contrast thresholds.

Elgohary et al. [39] used HHT to measure CS. They found a maximum improvement during the first 15 months of life with a slower progression until 36 months. The difference between the two results can be explained by the distribution of the groups in our study. The age range they comprise is very wide and may lead to greater variability in CS behavior between members of the same group due to that age difference which is critical in certain stages of visual development. Differences with our CS outcomes may also be related to differences in test design, stimuli and thresholds (HHT only measures until 1.9 log U while DIVE CS test reaches 3.00 log U).

Visual outcomes may slightly differ depending on the test used, based on their stimuli features, distance of performance, stimuli presentation and environmental conditions [40]. Normal reference data and plots are required from every visual test for every age group to use them in clinical practice.

In order to validate the DIVE VA test, we compared the results of VA measured with DIVE and with LGT in children with normal and abnormal visual development. The mean difference found between the two tests (LGT and DIVE VA test) was -1.05 cpd with DIVE most frequently providing higher VA outcomes. However, disagreement among the two tests was not the same for all the age groups. Mean difference was only -0.19 cpd in infants younger than 1 year, while reached -1.65 cpd in 1 to 2 years' group. In our sample of children, LGT barely improved in 1 to 2 years' group, remaining mostly stable, while DIVE VA outcomes continued slowly improving in this group. We consider that it could be due to lack of interest in LGT in children aged 1 to 2 years, when they get easily distracted by faces or objects around them. This limitation may be overcome by some features of DIVE test, such as the performance in a dark room, the attentional getters during the test and the positive feedbacks (a star with sound on the screen) obtained when they found the target.

The main strength of our study is the use of an electronic device with eye-tracking technology, an objective method for assessing gaze movements without the need of any verbal response from the child. The use of DIVE device gives us a wide range of possibilities and advantages: stimuli adapted to children of different ages and visual function, higher control of lighting conditions due to the calibration of the display, used of FPL paradigm with 3 distractors versus 1 as in the classic form [41] and reduction in time of exam, using an adaptive psychophysical method that optimizes the evaluation performed.

The principal limitation we found is the small sample size. It would be desirable to build normal values with a larger sample. It would also be interesting to study the repeatability of DIVE in the evaluation of VA and CS. The DIVE VA test allows a maximum stimulus of 18 cpd at the measurement distance, which could give rise to a ceiling effect in older children. Among all the possible exam frequencies for CS provided by DIVE, we chose the spatial frequency of 0.5 cpd since it is the most sensitive for newborn children because it is used in facial recognition [42]. However, in order to perform a complete exam, it would be recommendable to evaluate different spatial frequencies (low, medium and high) especially in children from 2 years of age.

There is a limiting lack of validated tools for young children who cannot communicate, which turns diagnoses and follow-up of visual disorders in childhood into a challenge. DIVE is an automatic, accurate and fast tool to assess several visual parameters in pediatric population without the need of an experience examiner. Future studies including more participants and more visual disorders would be desirable to clinically validate the tool.

DECLARATIONS

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Conflicts of interest:

The authors Pueyo V, Ortin M and Gutiérrez D are co-founders of the Dive Medical S.L., while Fanlo-Zarazaga A is a clinical experience specialist for that company.

Availability of data and material:

The corresponding author will answer reasonable requests for raw data and complete material.

Code availability:

Main features of the developed software are registered and we are not allowed to share them due to Intellectual Property issues. However, the authors will answer as far as they can to questions related to the software.

Ethics Approval:

All procedures during the study were approved by the local ethics committee: CEICA(PI15/0157).

Informed consent:

Informed consent was completed by the parents of all participants in this study, who also accepted the inclusion of their children in the study and the publication of the results.

Author's contributions:

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Pueyo V, Pérez-Roche T and Esteban-Ibañez E. The first draft of the manuscript was written by Esteban-Ibañez E and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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FIGURES:



Fig.1 Grating VA test in DIVE (DIVE VA test). Four circular stimuli: three grey distractors with different luminance between them and one target with a black and white vertical stripes pattern with maximum contrast



Fig.2 Grating CS test in DIVE (DIVE CS test). Four circular stimuli: three grey distractors with different luminance between them and one target with vertical grating (0.5 cpd) with different levels of contrast



Fig.3 Scatter plot of DIVE VA test outcomes plotted against Age. Pearson's correlation coefficient ρ (p-value) and trend line equation



Fig.4 Scatter plot of DIVE CS test outcomes plotted against Age. Pearson's correlation coefficient ρ (p-value) and trend line equation



Fig.5 Bland-Altman plot: comparison between LGT and DIVE VA test. Mean difference between both test (solid line) and 95% limits of agreement (LoA) (dashed line). Each age group is represented with different spot color: blue (<1 year), red (1-2 years) and green (>2 years)

TABLES:

	n	Mean (SD)	CI (95%)	Min. Value	Max. Value
Overall	57	10.92 (5.86)	9.36 – 12.47	0.25	18.00
<2 year	21	6.44 (4.33)	4.47 – 8.41	0.25	17.31
2-4 years	22	12.92 (5.29)	10.57 – 15.27	0.25	18.00
>4 years	14	14.49 (1.22)	11.86 – 17.12	4.00	18.00

DIVE VA test values (cpd)

 Table 1 DIVE VA test values of each age group and overall sample: mean, standard deviation, confidence interval (CI 95%), minimum and maximum value

	n	Mean (SD)	CI (95%)	Min. Value	Max. Value
Overall	44	1.57 (1.41)	1.34 – 1.79	0.13	2.63
<2 years	12	0.89 (0.50)	0.57 – 1.20	0.13	1.56
2-4 years	20	1.62 (0.71)	1.28 – 1.95	0.19	2.62
>4 years	12	2.17 (0.37)	1.94 – 2.40	1.44	2.63

DIVE CS test values (log U)

 Table 2 DIVE CS test values of each aged group and overall sample: mean, standard deviation (SD), confidence interval (CI 95%), minimum and maximum value

valuation values (cpu)							
	Test	n	Mean (SD)	CI (95%)	Average Tests (SD)	Difference Tests (SD)	
Overall	LGT	69	6.03 (3.33)	5.23 – 6.83	6.56 (2.95)	-1.05 (4.54)	
	DIVE VA		7.08 (4.08)	6.10 - 8.06			
< 1 year	LGT	25	5.64 (3.30)	4.28 – 7.00	5.74 (2.73)	-0.19 (4.02)	
	DIVE VA		5.83 (3.48)	4.40- 7.27			
1-2 years	LGT	25	5.43 (2.20)	4.67 – 6.18	6.25 (2.08)	-1.65 (4.37)	
	DIVE VA	55	7.07 (5.08)	5.82 - 8.33			
> 2 years	LGT	9	9.44 (3.36)	5.54 – 13.35	10.00 (4.16)	-1.12 (6.46)	
	DIVE VA		10.56 (5.46)	6.37 – 14.76			

Validation values (cpd)

Table 3 Validation values of each age group and overall sample: mean LGT test, mean DIVE VA test, standard deviations, confidence interval (CI 95%), average and mean difference between tests (LGT and DIVE VA test)