·Clinical Research·

Adult reference values of the computerized diplopia test

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Abstract

• AIM: To estimate the adult reference values for measured deviations by a computerized diplopia test and testify the validity.

• METHODS: Totally 391 participants were recruited and taken the computerized diplopia test. The plots and amplitude of deviations were recorded. The differences in different gender, age and visual acuity groups were analyzed respectively. Of 30 subjects were enrolled to testify the interobserver reliability. Another 46 subjects (including 26 normal subjects and 20 patients) were taken the test and theirs deviations were recorded to testify the validity of the reference value.

• RESULTS: The max horizontal and vertical deviations were 2.55° and 0.76° with normal corrected visual acuity while 3.88° and 1.46° for subjects with poor corrected vision. The differences between age groups was insignificant (Z=3.615, 4.758; P =0.461, 0.313 for horizontal and vertical respectively). The max horizontal deviation of female was smaller than male (Z=−2.177; P=0.029), but the difference in max vertical deviation was insignificant (Z=−1.296; P=0.195). The mean difference between observers were both −0.1°, with 95% confidence limits (CI) of −1.4° and 1.6° in max horizontal deviations while −2.1° and 1.8° in max vertical deviation. The mean deviation of 26 normal subjects was 1.02° ±0.84° for horizontal and 0.47°±0.30° for vertical which both within the range of reference values. The mean deviation of 20 patients was 13.51°±11.69° for horizontal and 8.34°±8.58° for vertical which both beyond the reference range.

• CONCLUSION: The max amplitude of horizontal and vertical deviation is pointed as the numerical parameters of computerized diplopia test. The reference values are different between normal corrected visual acuity and poor corrected vision. These values may useful for evaluating patients with diplopia in veriety conditions during clinical practice.

• **KEYWORDS:** computerized diplopia test; reference values; amplitude of deviations

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INTRODUCTION

Diplopia was the most commonly seen manifestation in patient with ocular motility disorders. Diplopia test could determine the direction of diplopia and rang of ocular movement, showing great value in clinical practice, especially in planning surgery [1] or acupuncture treatment[2]. In 1908, the Hess screen test was first invented [3], but manually perform and lack of firmly erect the patient's head caused inaccurate results[4-5]. Therefore, various modifications have been keep coming to the fore especially these versions based on computer software[6-7]. However, due to the changes in vergence could be recorded by the software, normal adults' test results showed fluctuations in different gaze directions [8]. This brings difficulties to distinguish patient who was present or remain mild diplopia symptoms to normal person. In order to determining the range of values as the references, we have tested 391 normal adults with the computerized diplopia test and testified the validity by another group of subjects. We hope it may useful for evaluating patients with diplopia in variety conditions during clinical practice.

SUBJECTS AND METHODS

Totally 391 normal adults were enrolled for determining the reference values, 30 normal subjects for interobserver agreement analysis and 46 subjects (26 normal adults and 20 patients with diplopia) for testifying the validity in our study from May 2015 to March 2016. Inclusion criteria for normal adult (20-69y) consisted of without strabismus, diplopia, ocular motility disorder, orbital disease, ocular or periocular operation history. The patients with diplopia consisted of a wide range of etiologies. The study followed the request of the Declaration of Helsinki and proved by Ethics Committee of the First Affiliated Hospital of Harbin Medical University. All the subjects were fully understand the aim and procedure of our study and signed the consent form.

Corrected Visual Acuity Totally 391 subjects' corrected visual acuity were measured by logarithmic visual acuity chart with the working distance of 5 m (GB11533-89, Suhong medical equipment company, Suzhou, Jiangsu Province,

China), the visual acuity in logarithm of the minimum angle of resolution (logMAR) were recored. During our clinical practice, most of the patients' corrected visual acuity were not better than 1.0. In order to determine how was the corrected visual acuity influence on the diplopia test, there was no limitation on corrected visual acuity.

Computerized Diplopia Test The device for applying the test contained three parts: head fixation frame, computer with projection system and software for the test[9] (Figure 1). The interactive software was based on Windows, while the test mode was as follows: 1 m working distance and 20° of ocular rotation from each target to the primary position. During the test, the patient was wearing red-blue glasses and then a red wafer showed up on one of the 9 gaze positions. The patient was asked to trap the red wafer with the blue circle cursor by moving the mouse. When the patient thought they were overlapped, the left mouse button was clicked and then the next point was appeared. After the 9 positions were all tested, the program would switch the color of wafer and circle and then repeat the same test procedure. All the participants expect these enrolled to determine the interobserver agreement were guided by the same doctor and self-paced to complete the test. The test results were stored in plot form and the amplitude of deviations, displacement between standard point and subjective recorded position, in 9 gaze directions were generated automatically.

Interobserver Agreement Totally 30 normal adults were enrolled and taken the computerized diplopia test twice. For each participant, the test procedure was guided and supervised by one of the observers (Li XM, Liu TJ) for the first visit. In the next day, the participants took the test again in the same order, but was guided and supervised by the other observer .

Validity of the Reference Values The validity of the reference values were testified by a group of 46 participants, including 26 normal subjects and 20 patients. The comuterized diplopia test was performed and the max deviations were recorded. By comparing the test results to the reference values, we testified if the normal adults maximum deviations were within the range and if the patients were beyond.

Statistical Analysis Statistic analysis was performed using SPSS for Windows (version 19.0, IBM, USA). The automatic generated deviations were shown as median (quartile) and the reference values were 95% confidence limits (CI). The Kruskal-Wallis test was used to analysis the differences of mean age and corrected visual acuity in age groups as well as the differences among amplitudes of 9 positions in horizontal or vertical direction for each eye. Differences between age groups, gender and visual acuity groups were analyzed by Mann-Whitney U test. The level of significant difference was P<0.05. The agreement of interobserver was analyzed by Bland-Altman plot.

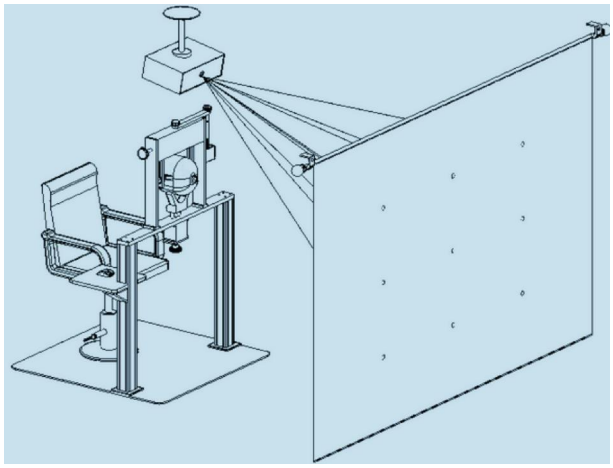

Figure 1 Schematic diagram of the device for applying the computerized diplopia test.

Table 1 The characteristics of the participants $\bar{x} \pm s$

Age groups (a)	n	Age (a)	Corrected visual acuity	
			Left eye	Right eye
20-29				
Male	59	23.97±2.79	0.7±0.28	0.7±0.27
Female	51	23.92±2.89	0.6±0.28	0.6±0.28
Total	110	23.95±2.82	0.7±0.28	0.7±0.28
30-39				
Male	42	23.97±2.79	0.7±0.31	0.7±0.29
Female	53	34.30±3.15	0.7±0.26	0.7±0.30
Total	95	34.22±3.04	0.7±0.28	0.7±0.29
40-49				
Male	43	44.33±2.51	0.8±0.31	0.8±0.28
Female	43	45.07±2.55	0.7±0.30	0.8±0.28
Total	86	44.70±2.54	0.7±0.30	0.8±0.28
50-59				
Male	42	54.07±2.61	0.7±0.26	0.7±0.23
Female	25	54.20±2.74	0.7±0.21	0.6±0.21
Total	66	54.12±2.64	0.7±0.24	0.7±0.23
60-69				
Male	21	62.71±2.78	0.7±0.23	0.7±0.22
Female	12	63.33±2.77	0.6±0.20	0.6±0.19
Total	33	62.94±2.74	0.7±0.24	0.7±0.24
Total groups	391	39.46±13.10	0.7±0.27	0.7±0.27
Male	207	40.28±12.78	0.7±0.28	0.7±0.26
Female	184	38.54±13.58	0.7±0.27	0.7±0.28

RESULTS

Our study enrolled 207 males and 184 females. The mean age was 39.46±13.10y. The characteristics of the participants in different age groups were shown in Table 1. There were no differences of mean age and corrected visual acuity in age groups (all P>0.05).

The differences among deviations in 9 gaze positions are shown in Table 2. Because the statistic analysis showed significant differences among the 9 gaze positions, we had chosen the max deviation of horizontal and vertical as the numerical parameters. Although there were differences of

Table 2 Differences among horizontal and vertical deviations for the 9 gaze positions of both eyes n=391

Gaze positions	Left eye		Right eye	
	Horizontal (°)	Vertical (°)	Horizontal (°)	Vertical (°)
Top left	0.31 (0.14, 0.58)	0.17 (0.08, 0.33)	0.25 (0.11, 0.48)	0.14 (0.07, 0.28)
Up	0.33 (0.22, 0.66)	0.31 (0.11, 0.42)	0.33 (0.11, 0.55)	0.21 (0.11, 0.42)
Top right	0.36 (0.17, 0.68)	0.16 (0.07, 0.30)	0.22 (0.11, 0.40)	0.15 (0.07, 0.30)
Left	0.31 (0.11, 0.62)	0.11 (0.11, 0.33)	0.31 (0.11, 0.52)	0.22 (0.11, 0.33)
Primary	0.35 (0.24, 0.59)	0.12 (0.12, 0.24)	0.24 (0.12, 0.47)	0.12 (0.11, 0.24)
Right	0.41 (0.21, 0.63)	0.11 (0.11, 0.22)	0.21 (0.11, 0.42)	0.11 (0.11, 0.22)
Bottom left	0.28 (0.12, 0.51)	0.14 (0.07, 0.25)	0.26 (0.11, 0.49)	0.15 (0.08, 0.26)
Down	0.33 (0.11, 0.55)	0.11 (0.10, 0.21)	0.22 (0.11, 0.44)	0.21 (0.10, 0.31)
Bottom right	0.28 (0.11, 0.47)	0.12 (0.05, 0.19)	0.21 (0.08, 0.39)	0.11 (0.05, 0.22)
χ^2	165.780	45.997	105.421	39.975
P	<0.001	<0.001	<0.001	<0.001
Max deviation	0.43 (0.29, 0.70)	0.21 (0.13, 0.36)	0.23 (0.21, 0.65)	0.21 (0.12, 0.33)
Z	-2.951[a]		-0.631[b]	
P	0.003[a]		0.528[b]	

Data are represented as median (quartile). [a]The values show the differences of max horizontal deviations between eyes; [b]The values show the differences of max vertical deviations between eyes.

horizontal deviations between eyes, as the left eye was slight larger than the right eye (Z=-2.951, P=0.003), the vertical deviations has no significant differences (Z=-0.631, P= 0.528).

By Mann-Whitney U test, we found that the deviations in different age groups had no significant difference (Z=3.615, 4.758; P =0.461, 0.313 for max horizontal and vertical respectively). The results were shown in Table 3.

The differences of max horizontal and vertical deviations between genders were significant by Mann-Whitney U test (Z=-2.177, -1.296; P=0.029, 0.195 for horizontal and vertical respectively). The deviations of female were smaller than male's. By Mann-Whitney U test, there were differences between different corrected visual acuity (Z=-3.076, -2.566; P =0.002, 0.010 for horizontal and vertical respectively). The participant with normal corrected visual acuity had smaller deviations than the one with poor corrected vision. The difference was so significant that the reference values should be distinguished from different group. The max horizontal and vertical deviations were 2.55° and 0.76° with normal corrected visual acuity while 3.88° and 1.46° for subjects with poor corrected vision. The results were shown in Table 4.

Interobserver reliability between the results of 2 observers were determined by Bland-Altman analysis. The differences of max horizontal and vertical deviation between Li XM and Liu TJ were -0.1°, with the 95% CI of -1.4° and 1.6° in max horizontal deviations (MHD) while -2.1° and 1.8° in max vertical deviation (MVD). The plot was shown in Figure 2.

The validity of the reference values was done by collecting 46 subjects' test parameters and comparing them to the reference values. In the 46 subjects, there were 20 patients diagnosed as ocular motility disorder and showed diplopia.

Table 3 Max deviation in horizontal and vertical in different age groups

Age groups (a)	n	HMAX (°)	VMAX (°)
20-29	110	0.56 (0.35, 1.00)	0.29 (0.20, 0.40)
30-39	95	0.51 (0.37, 1.07)	0.28 (0.21, 0.39)
40-49	86	0.48 (0.33, 0.87)	0.33 (0.21, 0.48)
50-59	67	0.57 (0.39, 0.90)	0.31 (0.22, 0.47)
60-69	33	0.62 (0.46, 1.19)	0.30 (0.22, 0.55)
Total	391	0.54 (0.37, 0.95)	0.29 (0.21, 0.43)
Z		3.615	4.758
P		0.461	0.313

Data are represented as median (quartile). HMAX: Max value of horizontal deviation; VMAX: Max value of vertical deviation.

All the dataset of the 20 patients were over the reference values and the plot was different in each subject. As the abducent nerve palsy example shown in Figure 3, the test parameters were 12.26 for MHD and 1.97 for MVD with the poor corrected visual acuity. In the 27 normal subjects, the max deviations were all fit in the range of reference values as the plot shown in Figure 4.

DISCUSSION

Diplopia, as the first sign of diseases mostly associated with myopathy or neuropathy [10], is usually cause the dysfunction of extraocular muscles (EOMs), where eyes cannot coordinately move to the target position [11]. To evaluate the severity of diplopia, a lot of testing methods have been invented including physical tests [12-16], questionnaire [17] and image tests[18-19], *etc.* Among the above methods, the diplopia tests, one of the physical tests, could directly reveal the range of ocular rotation for each eye. In 1990, Thomson *et al* [6] transfers the manual test into automated version for the first time. Watts *et al* [7] compared the ocular motility analyzer (OMA), a computerized Hess chart, with Lees screen test. The newest version was the computerized Lancaster red-green test [8]. However, all these versions were representing the

Table 4 Max deviations for different gender and visual acuity groups n=391

Parameters	n	HMAX (°)		VMAX (°)	
		Median (quartile)	95% CI	Median (quartile)	95% CI
Gender					
M	207	0.56 (0.35, 1.00)	<3.78	0.29 (0.20, 0.40)	<1.31
F	184	0.51 (0.37, 1.07)	<3.33	0.28 (0.21, 0.39)	<1.21
Corrected visual acuity					
>1.0	92	0.48 (0.33, 0.87)	<2.55	0.33 (0.21, 0.48)	<0.76
<1.0	299	0.57 (0.39, 0.90)	<3.88	0.31 (0.22, 0.47)	<1.46

Data are represented as median (quartile). HMAX: Max value of horizontal deviation; VMAX: Max value of vertical deviation.

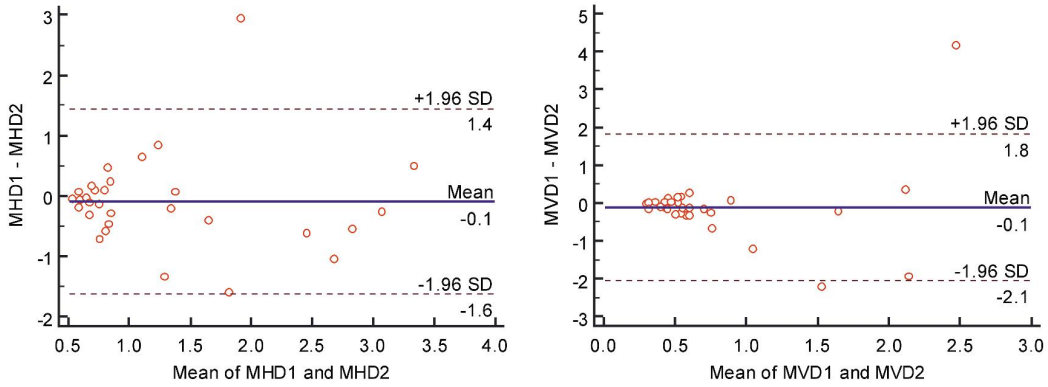

Figure 2 Interobsever reliability for the computerized diplopia test, assessed using the Bland-Altman strategy MHD1/2: Max horizontal deviation by Li XM/Liu TJ; MVD1/2: Max vertical deviation by Li XM/Liu TJ.

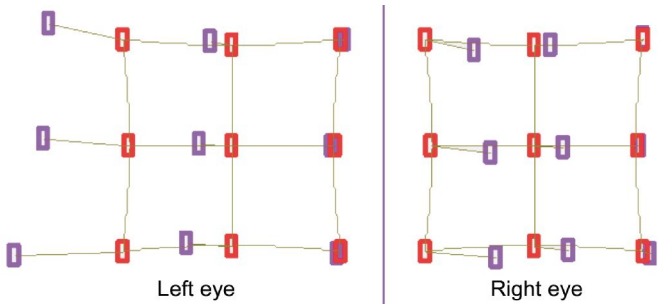

Figure 3 The plot of left abducent nerve palsy.

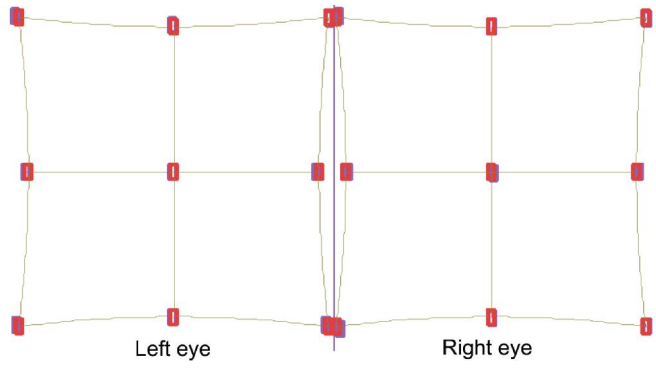

Figure 4 The plot of normal adult.

results in a plot form and a dataset contain too much parameter that was inconvenient as the reference values for clinical practice. Based on these, we were choosing the max horizontal and vertical deviations as the parameters of the test.

In the manual test, while interpreting the charts, there should be no displacement between target and the perceived one. The theoretical results of deviations should be absolute 0. However, by performing the test with our system, we found that normal adult exist deviations in different gaze positions. Ben Simon *et al*[20] and association studies showed the same results with healthy people's chart. In order to define the reference values of deviations, we recruited 391 normal adults to participate the investigation. On the basis of the data, we determined the reference values of normal adult, moreover, the max horizontal amplitude of deviations showed significantly differences compare to the max vertical one. We thought the causes of the above results include: 1) the Pamum fusion zone. As long as the target perceived was in the area of the Pamum fusion zone, no matter they were overlap or not, people could get one clear image; 2) the stimuli for applying the test were wafer and circle. The circle's diameter slightly larger than the dot, so when participants thought they were overlapped, there was still a small difference between the centers of the stimulus. When calculating the deviations by using the recorded coordinates of standard point and the perceived one, the deviation was not absolute 0; 3) the changes in vergence may influence the test results as described in Awadein[8] study.

Gender has great effect on normal function of human, especially for visual system. In our study, we found that the deviations of female were smaller than male's. These findings were also found in other researches. Lim *et al*[21] found that the angle of maximum version for males was significantly greater than that for females. The reason was considered as the different axial length between genders.

Age could be another factor which may have influence on the function of EOMs. Our results showed that the differences for vertical and horizontal deviations in different age group were insignificant.

More importantly, during clinical practice, we found that the awareness of keeping the normal corrected visual acuity has not been settled in by public. Most of patients visit our center were in poor corrected vision conditon. In order to investigate the differences between groups with different corrected visual acuity, we did not limit it as the Inclusion criteria. The results of statistic analysis showed larger deviations in the participants with bad eyesight.

During the test procedure, the guidance and supervise of the physician was important and may has influence on the patient's test results. In our study, we were using the Bland-Altman strategy for analyzing the interobserver reliability. The mean difference was -0.1 showing great agreement between observers.

In order to test the validity of the determined reference values, we enrolled 46 subjects. All the 26 normal adults got the results within the range while the other 20 subjects with diplopia showed larger deviations than the reference range.

In conclusion, the max amplitude of horizontal and vertical deviation was pointed as the numerical parameters of computerized diplopia test. The reference values were different between normal corrected visual acuity and poor corrected vision. These values may useful for evaluating patients with diplopia in veriety conditions during clinical practice.

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